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PRE CLINICAL AND CLINICAL

STUDY ON

AZHAL KEEL VAYU

(DISSERTATION SUBJECT)

For The Partial Fulfillment Of The

Requirements To The Degree Of

DOCTOR OF MEDICINE (SIDDHA)

BRANCH I - MARUTHUVAM

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Introduction

INTRODUCTION

Siddha system of medicine is the oldest among the Indian systems of medicine founded by siddhars and is also known as Tamil maruthuvam .

The origin of the siddha system dates back to BC 10,000- BC 4000, according to Thiru T.V Sambasivam pillai siddha medical dictionary.

The word ‘siddha’ comes from the word ‘siddham’ Siddha means ‘knowledge or wisdom’

Siddham means an object to be attained on perfection or ‘heavenly wisdom’ One who had attained perfection in life is called ‘siddhar’.

Siddhars were indeed true scientists who discovered and displayed god to the common people through their divine wisdom, medicines and elixirs with which they treated the incurable diseases of mankind.

Siddhars prepared varieties of medicines such as Parpam, Chenduram, Pathangam,Kattu, Kalangu, Chunnam, Satthu, Guru kuligai etc..From herbs,metals,minerals and animal products.

Siddha system is holistic system of medicine which treats individual both spiritually and physically. The treatment varies for different individuals based on their physical constitutions (Prakriti)

Siddha system of medicine classifies disease into 4448 types .According to this system of medicine , the human body is made up on three humours – vali, Azhal, Iyyam .In normal healthy condition ratio between them being 1:1/2:1/4.

“வழங்கிய வாதம் மாத்திரை யொன்றாகில்
தழங்கிய பித்தந் தன்னிலரை வாசி
அழங்குங் கபந் தானடங்கியே காலோடில்
பிறங்கியே சீவர்க்கும் பிச கொன்றுமில்லையே”

- குணவாகடம்

When the normal ratio of these humours – Vali, Azhal, Iyyam is disturbed, disease will occur.

மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளி முதலா எண்ணிய மூன்று. - திருக்குறள்

வளி வன்னியைக்கு வழங்கிடு மாத்திரை
ஒன்ரெரை காலா யோதினர் சித்தரே

மெய்யளவு வாதமொன்று
மேல் பித்த மோரரையாம் - கண்ணுசாமியம்

-

The factors which affect this equilibrium are environment, climatic conditions, diet and abnormal physical activities etc.

As per yoogi vaithiya sinthamani vatha disease is classified as 80 types. One such type is keelvayu otherwise called as Santhuvatham. As per sabapathy kaiyedu keelvayu is further classified into 10 types. One such type is Azhal keel vayu. As per sabapathy kaiyedu Azhal keel vayu is a disease with the symptoms of pain and swelling in the knee joints, fever difficulty in walking etc…it has the correlation with Osteoarthritis(OA) of modern science.

There are many diseases commonly affecting the middle aged and elderly people. One among them is Osteo arthritis which is given importance as it is mainly interfering with the principal function of human beings (i.e) locomotion.

The prevalence of OA in India is very high. The distribution of OA in men and women is similar. The prevalence of osteoarthritis between the age of 40-65 is 68% Approximately 4 out of 100 people are affected . Before age 45 more men have it, while after age 45 it is more common in women.60% of women are affected. Menopausal women are particularly prone to it.

Hence the author is interested to try effective remedy to this patients as said in Siddha literatures which the application of basic principles of Siddha and also supporting by modern parameters

The medicine chosen to this disease are **Sarva noi Linga Chenduram (Internal)** (Ref- **Anuboga** Vaithiya Navaneetham , Part 4,Hackim PA. Mohammed Abdullah Sayubu , Edition: pg no 52 &53 and Maasha thylum (External) (Ref- Vaithiya Sinthamani (Sigicha Rathina deepam Pg no:2C.Kannusamipillai Edition 2007

As per siddha text book the above said siddha formulations are found to possess antivatha property. They would be cost effective, efficacious and easy to prepare.

Aim and Objectives

AIM AND OBJECTIVES

AIM

The principal aim of the present study is

- ✓ To evaluate the therapeutic efficacy of the Siddha formulations sarva noi linga Chenduram (Internal) and Maasha thylam (External) in the treatment of Azhal keel vayu (Osteo arthritis).

OBJECTIVES

PRIMARY OBJECTIVE

- To evaluate the therapeutic efficacy of the Siddha drugs sarva noi linga Chenduram (Internal) and Maasha thylum (External) in reducing the pain in Azhal keel vayu (Osteo arthritis).

SECONDARY OBJECTIVE

- To conduct a clinical trial with a well defined proforma on the patients identified with "Azhal keel vayu ".
- To evaluate the safety of the test drugs (Acute and Sub acute toxicity studies) to be carried out as per WHO guidelines.
- To study the influence of other co factors such as age, sex, dietary habits, family history, socio economic status, habitat etc on the disease.
- To study Azhal keel vayu on the basis of

  (a) Mukkutram (b) Udalkattugal (c) Envagai thervugal etc
- To find out the side effects / adverse effects of the drug "SARVA NOI LINGA CHENDURAM (Internal) and MAASHA THYLUM (External)" if any.
- To screen the biochemical constituents of the drug.

Review of Literature

Siddha Aspects

LITERATURE REVIEW

SIDDHA ASPECTS

Universe originally consisted of atoms which contributed to the five basic elements (pancha boothas) namely Earth, water, fire, air, and ether which corresponds to the five sense of the human body and they were the fundamentals of all human body and all the corporal things.

The food we eat has six tastes namely sweet, sour, salt, bitter, pungent and astringent. Each of them is a mixture of five basic elements

இனிப்பு-	-	மண்	+	நீர்
புளிப்பு	-	மண்	+	தீ
உப்பு	-	நீர்	+	தீ
துவர்ப்பு	-	ஆகாயம்	+	மண்
கார்ப்பு	-	ஆகாயம்	+	தீ
கைப்பு	-	ஆகாயம்	+	விண்

Pancha poothas are the foundations for three humours (vaatham, piththam, kabam) which are the pillars that support our body structure.

Vaayu + Aagayam constitute vaatham

Theyu constitute piththam

Appu + Mann constitute kabam

Any alterations in the level of three humours affects the normal functions of the body.

AZHAL KEEL VAAYU

In Siddha literature Azhal keel vaayu described under vatha diseases. Keel vaayu is the general term that includes all kinds of joint disorders.

Description of the nomenclature

Azhal keel vaayu	=	Azhal + Keel + Vaayu
Azhal	=	Pitham
Keel	=	Joint
Vaayu	=	Vatham

Initially the joint is affected by the vitiated vatham. Pitham and kabam accompany later. It is a disease which is common in pitha kaalam (middle 1/3 of the lifespan).

TYPES OF KEEL VAAYU

Azal keel Vaayu is one among the ten types of Keel vaayu, which is mentioned in the text Siddha Maruthuvam, the ten types of Keel vaayu are:

1. Vali keel vaayu
2. Azhal keel vaayu
3. Iyya keel vaayu
4. Vali Azhal keel vaayu
5. Vali Iyya keel vaayu
6. Azhal Vali keel vaayu
7. Azhal Iyya keel vaayu
8. Iyya Vali keel vaayu
9. Iyya Azhal keel vaayu
10. Mukkutra keel vaayu

AETIOLOGY

SEASONAL FACTORS:

"வாதவர்த் தனைகால மேதோ வென்னில்
மருவுகின்ற ஆனிகற் கடக மாகும்
ஆதலைப் பசியோடு கார்த்திகை தன்னில்
அடருமே மற்றமா தங்கள் தன்னில்
போதவே சமிக்கின்ற கால மாகும்."

யூகி வைத்திய சிந்தாமணி

It is said that the vatha diseases are precipitated in the months from Aani to Karthigai (June to December), hence the seasonal factors are involved and facilitate the vatha diseases.

"பதுமத்தைப் பூக்க வைக்கும் பானுமிகக் காயும்
முதுவேனி லிற்புவிநீர் முற்றும் - கதுமென
வற்றும் கபமிகும் வாயுமிகும் வாழ்மாந்தர்க்
குற்ற நலிக் கேதிதென் றோது" - சித்த மருத்துவாங்க சுருக்கம்

In muthuvenil kalam the increased solar radiation increases the evaporation of water content from the body in turn increases the kabam and vatham thathus resulting in the production of vali diseases.

DIET

வளிதரு காய்கிழங்கு வரைவிலா தயிலல் கோழை
புளிதயிர் போன்மிகுக்கு முறையிலா வுண்டி கோடல்
குளிர் தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர்
களிதரு முயக்கம் பெற்றோர் கடிசெயல் கருவியாமால்"

- சபாபதி கையேடு

Vatha disease is caused due to the following reasons:

- Excessive intake of tubers
- Excessive intake of chill foods
- Wandering in chill air
- Getting drenched in rain
- Living in hilly region
- Excessive sexual desire and
- Heredity

"தொழில் பெறு கைப்புக்கார்த்தல் துவர்த்தல் விசுங்கினுங்சோறும்
பழையதாம் வரகு மற்றைப் பைந்தினை யருந்தினாலும்
எழில் பெறப் பகலுறங்கி இரவினிலுறங்காத தாலும்
மழைநிகா குழலினாலே வாதங்கோ பிக்குங் காணே"

- பரராசசேகரம்

Excessive intake of bitter,pungent, astringent and acrid taste food, intake of varagu, thinai and altered sleep pattern also contribute to vatha disease.

In Agathiyar kanma kaandam..,

வாத கன்ம வரலாறு

நூலென்ற வாதம் வந்த வகி தானேது

நுண்மையாய்க் கன்மத்தின் வகையைக்கேளு

காலிலே தோன்றியது கடுப்பதேது

கைகாலில் முடக்கியது வீக்கமேது

கோலிலே படுக்கின்ற விருட்சமான

குழந்தைமரந் தனைவெட்டல் மேல்தோல் சீவல்

நாலிலே சீவ செந்து கால் முறித்தல்

நல்லகொம்பு தழைமுறித்தல் நலித்தல் காணே

- கன்ம காண்டம்

According to Agathiyar kanma kaandam, cutting young trees and fracturing the legs of animals will produce Vatha diseases.

VATHA DISEASES

பொற்றா மரையான் புனைமெய் யரண்காக்கும்

பொற்றா மரையான் புகல்வதென் பொற்றாம்

வளவினிலே யாக்குரம்பை மன்னென்ன மன்ன

வளவினிலே யாக்கும் வளி

- தேரையர் யமக வெண்பா

As per Theraiyar, Vatham is being hailed as the king, who rules the fort (Body) and enables the dwelling of the citizen (Uyir) in the fort. Hence Theraiyar lauds Vatham as the prime force in normal state.

HABITS:

"வெய்யிலில் நடக்கை யாலும் மிகத்தண்ணீர் குடிக்கையாலும்

செய்யிழை மகளி னானைச் சேர்ந்தனுப விக்கையாலும்

பையவே உண்கை யாலும் பாகற்காய் தின்கையாலும்

தையலே வாத ரோகஞ் சனிக்குமென் றறிந்து கொள்ளே"

- தேரையர் வாகடம்

The factors like, walking under hot sun, increased sexual desire, and excessive in take of water and bitter guard etc, also disturbs the normal functions of Vaatham.

"தானென்ற கசப்போடு துவர்ப்பு றைப்பு
சாதகமாய் மிஞ்சுகிலுஞ் சமைத்த வண்ணம்
ஆனென்ற வாறனது பொசித்தலாலும்
ஆகாயத் தேறலது குடித்தலாலும்
பானென்ற பகலுறக்க மிரா விழிப்பு
பட்டினியே மிகவுறுதல் பார மெய்தல்
தேனென்ற மொழியார் மேற்சிந் தையாதல்
சீக்கிரமாய் வாதமது செனிக்குந் தானே"

- யூகி வைத்திய சிந்தாமணி

Excessive intake of bitter, astringent, pungent taste, excessive intake of food, intake of rain water, altered sleep rhythm, increased starvation and increased sexual desire will produce vatha diseases.

CHARACTERS OF VATHA DISEASES:

"வாதமே கதித்தபோது வாய்வு எழும்புங் கண்டீர்
வாதமே கதித்தபோது வந்திடுஞ் சன்னி தோடம்
வாதமே கதித்தபோது வந்திடும் வியாதி மேலும்
வாதமே கதித்தபோது வல்லுடல் மெலிந்து கொல்லும்"

- அகத்தியர் சிகிச்சா ரத்ன தீபம்

When vatham increases gsses increases, many diseases may arise like sanni, body loses the weight.

"வாத வீறு அன்னமிறங்காது கடுப்புண்டாம் வண்ணமுண்டாம்
மோதுகட்டு ரோகம் சுரமுண்டா மிருமலுமா முறங்காதென்றும்
ஓது சூரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள் களாய்த்
தீதெனவே நரம்பிசித்து சந்துகள் தோறுங்கடுக்குந் தினமுந்தானே"

- (தேரையர் வாகடம்)

When the Vatha kutram aggravates it will produce the following signs and symptoms:

- loss of appetite,
- Excruciating pain
- Fever
- Cough,
- Insomnia
- Shivering of the body
- Nervous weakness
- Joint pain

" காணப்பா வாதமீறில் கால்கைகள் பொருத்து நோவும்
பூணப்பா குடல்புரட்டும் மலசலம் பொருமிக் கட்டும்
ஊணப்பா குளிருங் காய்ச்சல் உடம்பெல்லாம் குத்துவாய்வு
வீணப்பா குதமிறுக்கும் வியர்வையும் வேர்க்கும் தானே "

-அகத்தியர் வைத்திய காவியம்

According to **Agathiyar vaithiya Kaaviyam**, the deranged vali produces pain in the joints of the hands and legs, flatulence, constipation, scanty micturition, fever with rigor, generalized body pain and increased sweating.

" தக்க வாயு கோபித்தல் சந்து வுளைந்து தலைநோவா
மிக்க மூரி கொட்டாவி விட்டங் கெரியு மலங்கட்டும்
ஒக்க நரம்பு தான்முடங்கு முலர்ந்து வாய்நீ ருறிவரும்
மிக்க குளிரும் நடுக்கமுமாம் மேனி குன்றி வருங்காணே"

- தேரையர் வாகடம்

According to **Theraiyar vagadam**, the deranged vali produces pain in the joints, head ache, constipation, increase salivation, fever with rigor and loss of normal complexion.

"ஆகங்கறுக்குநோ யாகந் துடிக்கும்
ஆறாத்தீ யென்னமெய் யேகங் கொதிக்கும்
ஆருமெய் வியர்தியிர் மீமந்தம் வாய்மூச்சு
ஆகுமேயிது வாதமேலினி "

-தேரையர் கரிசல்

According to **Theraiyar karisal**, the deranged vali produces blackish discolouration of body, feverishness, increased sweating, indigestion and dyspnoea.

மேவியவாதஞ் செய்யுங் குணந்தனை வியம்பக் கேளாய்
தாவியே வயிறு மந்தஞ் சந்துகள் பொருத்து நோவாஞ்
சீவிய தாதுநாசஞ் செறுத்துடன் சிறுநீர் வீழுங்
காவியங் கண்ணி னாளே மலமது கருகி வீழும்."

"வாதத்தின் குணமேதென்னில் வயிறது பொருமிக்கொள்ளுந்
தாதுகளுலர்ந்து கைகால் சந்துகள் கடுப்பு தோன்றுந்
தீதுற்றச் சிறுநீர்தானுஞ் சிறுத்துடன் கடுத்து வீழும்
போதுற்ற வாதமென்று புகன்றனர் முனிவர் தாமே".

அகத்தியர் வாத காவியம் 1000

According to **Agathiyar vatha Kaaviyam 1000,** the deranged vali produces abdominal discomfort, pain in joints, oliguria, dysuria, constipation and flatulence.

SITES OF VALI

வாதம் வாழுமிடம் - The sites of vali

" நெளிந்திட்ட வாதமபா னத்தைப் பற்றி
நிறைந்திடையச் சேர்ந்துந்திக் கீழே நின்று
குளிர்ந்திட்ட மூலமதூ டெழுந்து காமக்
கொடியிடையைப் பற்றியெழுங் குணத்தைப் பாரே !

"குணமான வெலும்பைமேற் றொக்கை நாடி
நிணமான பொருத்திடமும் ரோமக் காலும்
நிறைவாகி மாங்கிசமெல் லாம்பரந்து
கால்கட்டி வாதமெங்குங் கலக்குந் தானே !"

- வைத்திய சதகம்

According to **vaithiya sathagm**, vatham dwells in the following places: Umbilicus, rectum, faecal matters, abdomen, anus, bones, hipjoints, skin, navel plexus,Joints, Hair follicles and muscles.

" அறிந்திடும் வாத மடங்கு மலத்தினில்"

- திருமூலர்

நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்

நாபிக்கு கீழென்று நவில வாகும்.

- யூகிமுனிவர்

According to **sage Thirumoolar and sage Yugi**, the places of vatham are the anus and below the navel region.

அபானமுத லுந்தி வரை வாதநிலை

உந்தியின் மேல்மார்பு மட்டும் பித்தநிலை

-அனுபோக வைத்திய பிரம்ம ரகசியம்

According to **Anupoga vaithiya bramma ragasiyam**, vatham exists between the umbilicus and navel region.

Properties of Vali*:*

ஒழுங்குடனே தாதேழ் மூச்சோங்கி இயக்க

எழுச்சி பெற எப்பணியுமாற்ற எழுந்திரிய

வேகம் புலன்களுக்கு மேவச் சுறுசுறுசுறுப்பு

வாகளிக்கும் மாந்தர்க்கு வாயு

-சித்த மருத்துவாங்கச் சுருக்கம்

Natural properties of Vatham: [Ref: Noi Nadal part-1]

1. Giving briskness
2. Expiration and Inspiration
3. Functioning of the mind, thoughts and body
4. Regulation of the “Fourteen Physiological Reflexes”(Vegam).
5. Functioning of the “Seven Udal Kattukal” uniformly
6. Protection and strengthening of the five sensory organs. (Iymporigal)

Symptoms of Vatham thodam:

1. Body ache
2. Pricking pain
3. Tearing pain
4. Nerve weakness
5. Mental distress
6. Movements
7. Joints pain
8. Traumatic pain
9. Dislocation of joints
10. Weakness of organs
11. Paralysis of limbs
12. Polydypsia
13. Severe pain in calf and thigh muscles
14. Bony pricking pain
15. Anuria and constipation
16. Unable to do flexion and extension of the limbs
17. All tastes to be like astringent
18. Excess Salivation

வாதத்தின் குணங்கள்

- கடினம் - Rough
- வறட்சி - Dry
- இலேசு - Light
- குளிர்ச்சி - Cold
- அசைதல் - Unstable
- அணுத்துவம் - Subtl

வாதத்தை நீக்க கூடிய குணங்கள்

- மிருது - Soft
- பசுமை - Unctuous
- பளுவு - Heavy
- அக்கினி - Hot
- ஸ்திரம் - Stabl
- கெட்டி - Solid

வாத தேகியின் இலக்கணம்

- மெலிந்து உயர்ந்த உடல்
- நடந்தால் கீல்கள் நெட்டையிடுதல்
- கருமை வெண்மை கலந்த உடல் நிறம்
- தடித்த இமைகள்
- வெண்மை கலந்த கண்கள்
- இனிப்பு, புளிப்பு, உப்பு சூடான பொருள்களிலும் விருப்பம்
- புத்திர பெருக்கம்
- தொக்கணம், வேட்டையாடல் இவைகளில் வெறுப்பு
- அரைக்கண் தூக்கம்

In Azhal keel vayu

NAME	LOCATION	PHYSIOLOGICAL FUNCTIONS
Abanan	Lower abdomen and Extremities	Responsible for urination, defecation and parturition, Menstruation, ejaculation of the sperm.
Viyanan	Heart	Responsible for movements of all parts of the body and sensation.
Samanan	Stomach	Responsible for proper digestion

- Abanan is affected and so constipation is produced.
- Viyanan is affected it renders difficulty in movements of the knee joints.
- Samanan is also affected because disturbed state of other vaayus

அழல் கீல் வாயு நோய் குறிகுணங்கள்:

"பித்தகீல் வாய்வு தன்னாற்
பிறங்கு கீல்மூட்டு வீங்கிச்
சித்தர்செய் மருத்து வத்துஞ்
சீர்படாத் தன்மை தாகித்
தத்தறு காய்ச்சல் கண்டு
சாலவே தனைதான தந்தே
மெத்தறு சிகிச்சை தன்னால்
மென்மேல் நீங்கு மப்பா" - சபாபதி கையேடு

It is characterized by swelling of joints associated with severe pain and pyrexia. Since it is not quickly responding to medicine the prolonged medical care is said to be essential. As pitha increases kaba (mucous) in the joint decrease and hence dryness occur. So, during flexion of the joint crepitation is produced**.**

நோய் கணிப்பு- Diagnosis in Siddha:

Piniyari muraigal (Method of Diagnosis) is based upon three main principles,

1) Poriyal Arithal(Inspection)
2) Pulanal Arithal (Palpation)
3) Vinaathal(interrogation)

1. Poriyal Arithal (Inspection):

"Poriyal arithal" means examining the "Pori" of the patient by the "Pori" of the physician for proper diagnosis. Pori is considered as the "Five sense organs" of perception namely,

1) Mei (Skin)
2) Vai (Tongue)
3) Kan (Eye)
4) Mookku (Nose)
5) Sevi (Ear)

2. Pulanal arithal (Palpation):

Pulan are five object of senses. They are,

1) Smell
2) Taste
3) Vision

4) Sensation of touch
5) Hearing

"Pulanal arithal" means examining the "Pulan" of the patient by the "Pulan" of the Physician to diagnose a disease.

3.Vinaathal (Interrogation):

Vinaathal is gathering information regarding the history of disease, its clinical features etc., from the patient or his/her close relatives useful when the patient is not in a position to speak or in the case of a child.

ENN VAGAI THERVUGAL (Eight diagnostic Tools):

It is a unique method of diagnosis in Siddha system of medicine. They are clearly explained by Siddhar Theraiyar

"மெய்க்குறி நிறம் தொனி விழி நா இருமலம் கைக்குறி"

- தேரையர்

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

-நோய் நாடல் நோய் முதல் நாடல் திரட்டு,பாகம் 1

Hence the diagnosis is made by the following

1. Naadi (pulse)
2. Sparisam (sensation to touch)
3. Naa (tongue)
4. Niram (colour)
5. Mozhi (voice)
6. Vizhi (eyes)
7. Malam (faeces)
8. Moothiram (urine)

Azhal keel vayu in relation with Envagaithervugal,

NAADI :

உடலில் உயிர் தரித்திருப்பதற்கு காரணமான சக்தி எதுவோ அதுவே தாது அல்லது நாடி எனப்படும்.

"நாடி என்றால் நாடியல்ல நரம்பில் தானே,
நலமாக துடிக்கின்ற துடிதானு மல்ல,
நாடி என்றால் வாதபித்த சிலேற்பனமு மல்ல
நாடி எழுபத் தீராயிரந் தானு மல்ல
நாடிஎன்றால் அண்டரெண்டமெல்லாம்
நாடி எழுவகைத் தோற்றத்துள்ளாய்நின்ற
நாடியது யாராய்ந்து பார்த்தா ரானால்
நாடியுறும் பொருள்தெரிந்து நாடுவாரே"

- பதிணென் சித்தர் சதகநாடி நூல்

Naadi is responsible for existence of life and can be felt one inch away from the wrist joint on radial side by means of palpation with the tips of index, middle and ring fingers corresponding to vaatham, pitham, kabam respectively.

The three humors vaatham, piththam and kabam exisits in the ratio 1:½ :¼ normally. Derangement in these ratios leads to various disease entities.

The three " uyir thathukkal'' are formed by the combination of three nadigal with three vaayu.

a)	Edakalai	+	Abaanan	=	Vaatham
b)	Pinkalai	+	Piranan	=	Piththam
c)	Suzhumunai	+	Samanan	=	Kabam

" திருத்தமாம் வாதத் தோடே தீங்கொடு பித்தம் சேரிற்
பொருத்துகள் தோறும் நொந்து போதவே பிடிக்கும் "

- நோயின் சாரம்

When piththa gets vitiation it accompany with vatha and causes pain in every joints.

“ வாட்டிடும் சேத்துமத்தில் வந்திடும் வாதமாகில்

நாட்டிய கால்கள் போல நரம்பெல்லாம் வலித்து நிற்கும் “

- அகத்தியர் நாடி

When kapha and vatha are vitiated pain occurs in the nerves and lower extremities.

“ காணப்பா வாத மீறில் கால்கைகள் பொருந்தி நோகுமே ”

- காவிய நாடி

When vatha gets vitiation pain occurs in the joints and lower extremities.

“ வாதத்தில் சேத்துமமாகில் வலியோடு வீக்க முண்டாம் ”

- அகத்தியர் நாடி

When kapha vitiated with vatha, it causes pain and swelling in the joints.

“ சொல்லிய ஐயத்தோடே பித்தமங் கூடிற் றானால்

சல்லியம் போலக் குத்தும் மைந்தனே எலும்பும் தோலும்”

- காவிய நாடி

When piththa vitiated with kapha it results in stabbing pain in bones and joints.

In Azhal Keel Vayu the following types of naadi can be seen commonly.

They are,

a) vaatha piththam

b) vaatha kabam

c) piththa vaatham

d) piththa kabam

e) kaba vaatham

2. Sparism (Sensation to touch):

In Azhal keel vaayu mild warmth noticed over the affected joint.

3. Naa (Tongue):

In Azhal keel vaayu no abnormality is seen in Naa.

4. Niram(Colour):

In Azhal keel vaayu no abnormality is seen in Niram.

5. Mozhi:

It constitutes high, low-pitched voice, nasal speech, hoarseness of voice slurring and incoherent speech etc.

In Azhal keel vayu no abnormatlities are seen normally.

6. Vizhi:

Both motor and sensory disturbance of eye are noticed. Redness of eyes, paleness, excessive lacrimation, swelling, corneal ulcers, sunken eyes may be noted for.

In Azhal keel vayu no abnormatlities are seen normally. In anaemic patients pale conjunctiva may be noted.

7. Malam:

Vatha type: Black coloured stools with constipation.

Pitha type: Loose stools with yellowish red colour

Kabha type: White coloured stools with mucous

Thontha type: Stools possess some of the features of two thodams

In Azhal keel vayu constipation was reported in some of the cases.

VIII. Moothiram:

Neerkuri and Neikuri (Oil on urine sign) are special diagnostic methods regarding urine (Moothiram).

Neerkuri and Neikkuri:

"அருந்து மாறிரதமும் அவிரோதமதாய்
அ◌ீகல் அலர்தல் அகாலவூண் தவிர்ந்தழற்
குற்றள வருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியே காதுபெய்
தொருமுகூர்த் தக்கனலக் குட்படுநீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

-சித்த மருத்துவாங்க சுருக்கம்

Prior to the day of urine examination the patient is instructed to take a balanced diet and quantities of food must be proportionate to his routine intake. The patient could have no disturbed sleep. After waking up in the morning, the first urine

voided is collected in a clear wide mouthed glass bowel and is subjected to analysis of "Neerkkuri and Neikkuri" within one and a half an hour.

வந்த நீர்க்கரி எடை மணம் நுரை எஞ்சலென்
றைந்திய லுளவை யறைகுது முறையே "

சித்த மருத்துவாங்க சுருக்கம்

Voided urine has the following characters

1. Niram - Colour
2. Edai - Specific Gravity
3. Manam - Smell
4. Nurai - Frothy nature
5. Enjal - Deposits

Apart from these , the frequency of urination , abnormal constituents , such as sugar, protein, presence of blood, pus, also to be found out.

In Azhal keel vayu patient straw coloured urine was noticed.

Neikuri:

The speciality of Neikuri is stated in the following verse.

"ஐயக்குறி கொடுவட வானிழ லமர்ந்தோர்
கைக்குறி தெரித்த நங்கடவுளைத் துதித்தே
மெயக்குறி நிறந்தொனி விழிநா இருமலம்
கைக்குறி முழுவதூஉங் கற்றார் தம்மினும்
பொய்க்குறி மெய்க்குறி புகலு மெவர்க்கும்
நெய்க்குறி அதனை இந்நீணிலத் துரைப்பாம்"

- நோய் நாடல் நோய் முதனாடல் திரட்டு பாகம் 1

The process of dropped gingely oil indication

" நிறக்குறிக் குரைத்த நிருமண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்

தென்றுறத் திறந்தொலி ஏகாதமைத்ததி

னின்றதிவலை போம் நெறிவிழியறிவும்

சென்றது புகலுஞ் செய்தியை யுணரே"

- நோய் நாடல் நோய முதனாடல் திரட்டு பாகம் 1

The collected specimen was examined by the following method. The collected urine specimen is kept in a glass bowel and observed under direct sunlight without shaking the vessel. Then drip one drop of gingely oil and observe the spreading pattern and concludes as follows**,**

அரவென நீண்டின் அஃதே வாதம்

ஆழிபோல் பரவின் அஃதே பித்தம்

முத்தொத்து நிற்கின் மொழிவதென் கபமே

அரவில் ஆழியும் ஆழியில் அரவும்

அரவில் முத்தும் ஆழியில் முத்தும்

தோற்றில் தொந்த தோடங்களாமே"

- சித்த மருத்துவ நோய் நாடல் நோய் முதனாடல் திரட்டு,பாகம் 1

When the oil drops lengthens like a snake it indicates 'vatha Neer'

When the oil drops spreads like a ring it indicates 'pitha Neer'

When the oil drops remains that of pearl it indicates' kaba Neer'

PARUVAKAALAM (Seasonal variations):

S.No	STATE OF KUTTRAM	KAALAM
1.	Vatham thannilai adaithal	Munpani kaalam, Pinpani kaalam,Koothir kaalam, Elavenil kaalam
2.	Vatham thannilai valarchi	Muthuvenil kaalam
3.	Vatham vetrunilai valarchi	Kaarkaalam

Vatham vitiates during Muthuvenil, i.e during summer, the environment is hot it leads to dryness of the body and the body loses its energy through perspiration and may impair the digestion.

So, in Azhal keel vayu the disease shows its exacerbation during muthuvenil kaalam.

THINAI (Geographical Distribution):

It is divided into five types. They are,

S. NO	THINAI	LAND	AFFECTED HUMORS
1.	Kurinchi	Mountain and its surroundings Hilly terrain	Kabam
2.	Mullai	Forest and its surroundings Forest ranges	Pitham
3.	Marutham	Farm land and its surroundings Cultivable lands	All three humors are in equilibrium
4.	Neithal	Sea shore and its adjoining areas Coastal belt	Vatham
5.	Palai	Desert and its surroundings Arid zone	All three humors are affected.

நெய்தனில மெலுவர்ப்பை நீங்கா த்றினுமது
வெய்தனில மேதங்கு வீடாகும் - நொய்தீன்
மருங்குடலை முக்காக்கி வல்லுறுப்பைவீக்கும்
கருங்குடலைக் கீழிறிக்குங் காண்.

- பதார்த்த குண சிந்தாமணி

Geographical distribution plays a vital role in altering Mukkutrams. According to Siddha, vatha diseases are predominant in Mullai and Neithal Thinai.

UDAL KATTUGAL:

Our body consists of seven udal kattukal.

SL. No	UDAL KATTUGAL	FUNCTIONS
1.	Saaram	It gives strength to the body and mind.
2.	Senneer	Saaram after absorption is converted into senneer. It is responsible for knowledge strength, boldness and healthy complexion.
3.	Oon	Gives structure and shape to the body and is responsible for the movements of the body.
4.	Kozhuppu	Lubricates the organs on its own works.
5.	Enbu	Protects the vital organs and used for movements and nominates the body structure.
6.	Moolai	Present inside the bones and it gives strength and maintains the normal Condition of the bone.
7.	Sukkilam(or) suronitham	Responsible for the reproductive function of species.

S.no	**UDAL KATTUKAL**	**INCREASED CONDITIONS**	**DECRESED CONDITIONS**
1	Saaram	Loss of appetite, excessive salivation,diminished activity, heaviness, pallor, cold, decreased physical constituents, dyspnoea, flatulence, cough, excessive sleep.	Tiredness,dryness of skin, Laziness, loss of weight, lassitude, and irritability while hearing heavy noise.
2	Senneer	Boils and tumours in different Parts of the body, Spleenomegaly, pricking pain, increased blood Pressure, reddish eye and skin, jaundice, leprosy, haematuria etc.	Affinity to sour and cold food, nervous debility, dryness , pallor.
3	Oon	Tubercular adenitis, Tumours or extra growth around the neck, cheeks, abdomen, thigh, genitalia.	Lethargic sense organs, pain in the joints, muscle wasting in mandibular region, gluteal region, penis, thighs.
4	Kozhuppu	Identical feature of increased flesh, tiredness, dyspnoea on exertion, extra musculature in gluteal region, external genetalia, chest, abdomen thighs	Loins Pain, spleenomegaly, emaciation.
5	Enbu	Excessive ossification and dentition	Joint pain, falling of teeth, falling and splitting of hairs and nails.
6	Moolai	Heaviness of the body and eyes, swollen inter phalangeal joints, oliguria and non healing ulcers.	Osteoporosis, Blurred vision.
7	Sukkilam or Suronitham	Increased sexual activity and signs identical to urinary calculi	Dribbling of sukkilam/ suronitham or senneer during coitus, pricking pain in the testis, inflammed and contused external genitalia.

In Azhal keel vaayu,

Saaram, Kozhuppu, Moolai and Enbu thathukkal are commonly affected.

Saaram	**:** Weakness, pain in knee joints
Kozhuppu	**:** Morning stiffness occurs in affected knee joints
Enbu	**:** Pain occurring in affected knee joints, crepitations present
Moolai	**:** Osteoarthritis in knee joints

UYIR THATHUKKAL:

Human body is influenced by three uyir thathukkal i.e, Vatham, Pitham and kabam. They are responsible for normal physiological conditions of the body.

Vatham

DESCRIPTION OF VATHAM:

The Siddha classical texts divide the general principles of Vatham into ten subsidiary forms that differ from one another by their localizion in the body (Anatomical) and by their particular functions (Physioloical). They are

1. **PRAANAN: (Heart Centre)**

It refers to be in the chest. It maintains the action of the heart, the functioning of the mental faculties of perception and concentrations and also cares for the arteries, veins and nerves. It regulates the respiration and digestion. It is otherwise called as "***Uyirkkaal".***

2. ABAANAN: (Moolaadharam Centre)

It corresponds to the *pelvic area* and controls the excretion. It is focussed in the lower part of the gut and also occupies the sites in the bladder and genitals. It has a tendency to travel downwards. It moves in the whole Genito Urinary Tract and regulates the defaecation, micturition, menstruation, parturition and ejaculation. It is otherwise termed as ***"Keezhnokkumkaal***".

3. VIYAANAN: (Fore head Centre)

It corresponds to the *naso cilary area i.e* at the root of the nose and base of the skull and controls the will. It helps in the circulation of energy throughout the entire nervous system and the movements of various parts of the body. It also transports nutrients and blood throughout the entire body. It is also known as ***"Paravukaal***."

4. UDHAANAN: (Throat Centre)

This corresponds to the *pharyngeal area* in the throat region and controls speech and breathing. It is also responsible for the physiological reflex actions like vomiting, hiccup, cough, etc. It has the tendency to travel upwards. It is otherwise named as "***Melnokkukaal.***"

5. SAMAANAN: (Navel Centre)

It corresponds to in the navel region and controls digestion. It selects the useful substances from the swallowed food and supplies them to the whole body. It balances the other 'Vayus" it is also called "***Nadukkaal."***

6. NAAGAN:

It is responsible for the intelligence of an individual, winking, singing and pilo erection.

7. KOORMAN:

It is responsible for yawning, closing of mouth (movement of lower jaw) winking, shedding of tears, vision and opening of the eyes.

8. KIRUGARAN:

It is responsible for salivation and nasal secretion. It helps in digestion and meditation. It produces cough and sneeze.

9. DHEVATHATHAN:

It is responsible for laziness, lassitude, quarreling, arguing, and also for much anger. It helps movements of the eyeball in various directions and is present in genital and anal region.

10. DHANANJEYAN:

It is present in nose and responsible for swelling of the body and tinnitus. It leaves the body by blowing up the cranium only on the third day after death.

[Ref: Siddha Maruthuvanga Churukkam]

Piththam

Piththam is responsible for all the transformation. piththam is located in urinary bladder,heart, umbilicus,abdomen,blood, sweat, skin and eyes.

Piththam is classified into 5 types.

1.Anala piththam	- Responsible for digestion of food
2.Ranjaga piththam	- Responsible for colour of blood
3.Sathagam	- Located in heart and is responsible for normal activities of the body.
4.Alosagam	- Responsible for normal vision
5.Prasagam	- Responsible for the complexion of skin

In Azhal keel vayu

Sathagam affected- Difficulty in walking, climbing upstairs, squatting, sitting cross legged (Daily activities).

Kabam

Stabilizes, maintain and lubricates the joints and helps in their movements.

Kabam is found in samanan, semen, brain, head, tongue, nose, bones, bone marrow, fat, nerves, chest, blood, large intestine, eyes, stomach and pancreas.

Kabam is clasiified in to 5 types they are

1. Avalambagam-	Heart is the centre for avalambagam. It controls all other Forms of kabam.
2.Kiletham-	Stomach is the center for kiletham. It give moisture and Softness to the ingested food and helps digestion.
3. Pothagam-	Tongue is the center for Pothagam and it is responsible for the sense of taste
4. Dharpagam -	Head is the center for Dharpagam. It gives cooling effect to eyes
5. Santhigam-	It lies in the joints and it is responsible for the locomotive action of movable bony joints.

In Azhal keel vayu ,

Santhigam affected - Produce difficulty in movements of the knee joints.

S.No	HUMOUR	INCREASE	DECREASE
1	Vatham	Distended abdomen, Constipation, weakness, Insomnia,tremors, guiddiness, Blackish discoloration of body	Body pain, feeble voice, syncope,diminished capability of brain, symptoms associated with growth of kabam.
2.	Piththam	Yellowish discoloration of eyes,Skin, urine and motion, Polyphagia, polydypsia, Burning sensation all over the body, sleeplessness.	Cold, Pallor, Decreased appetite.
3.	Kabam	Loss of appetite, excessive salivation, heaviness of body, Dyspnoea, excessive sleeping, Diminished activity.	Prominence of bone edges, Profuse, palpitation, sweating, Guiddiness, dryness of joints.

VARIATION OF MUKKUTRAMS

Vatham is mainly responsible for proper loco-motor functions. Bones and joints are considered to be the main location of vatha.

In Azhal keel vaayu the vatha kutram is mainly affected followed by pitham and Kabam. This produces the following signs and symptoms,

1. Deranged viyanan leads to pain and difficulty in movements.
2. Deranged Abanan leads to constipation.
3. Inflammatory changes of the joints, redness and warmth are developed due to deranged pitham.
4. Sathaga pitham gets affected hindering the loco motor functions.
5. Along with vatham, kabam is also deranged, i.e Santhikam is affected and this leads to abnormality in joint movements.
6. Erosions of bone margin, increased secretion of synovial fluid are developed due to deranged kabam.

IMPORIGAL:

Gnanenthiriyam are Mei, Vaai, Kan, Mooku and Sevi.

In Azhal keel vaayu no abnormalities are seen in Gnanenthiriyam

KANMENTHIRIYAM:

Kanmenthiriyam are Kai, Kaal, Vaai, Eruvaai, Karuvaai.

In Azhal keel vaayu “kaal” is affected and become of pain and swelling, morning stiffness and deformities.

KAALAM

Ancient Tamilians divided a year into six different seasons known as Perumpozhudhu and likewise the day into six segments which are known as Sirupozhudhu.

Perumpozhudhu:

A year is divided into six seasons. They are as follows

Sl.NO.	Season	Months	Kuttram
1.	Kaarkaalam	Aavani & Purattasi August 16 – October 15	Vatham ↑↑ Pitham ↑
2.	Koodhir kaalam	Ayppasi and kaarthigai October 16 – December 15	Vatham (-) Pitham ↑
3.	Munpani kaalam	Margali and Thai December 16 – February 15	Pitham (-)
4.	Pinpani kaalam	Maasi and panguni February 16 – April 15	Kabam ↑
5.	Elavenir kaalam	Chithirai and Vaigasi April 16 – June 15	Kabam ↑ ↑
6.	Mudhuvenir kaalam	Aani and Aadi June 16 – August 15	Vatham ↑ Kabam (-)

↑ - Thannilai valarchi (-) - Thannilai adaidhal

↑↑ - Vetrunilai valarchi

- In Kaarkalam Vatha diseases may occur greatly.
- In Muthuvenil kaalam it may worsen badly.

NOI KANIPPU VIVATHAM (DIFFERENTIAL DIAGNOSIS):

Azhal keel vaayu is differentiated from the followings diseases,

- **VALI KEEL VAAYU:**

வலிக்குத்தல் வீக்கங்காணும்
வாய்த்தொண்டை வறட்சி காய்ச்சல்
தலை வலி மார்த்துடிப்புத்
தாங்கொணா வலிவீக் கந்தான்
நிலவுகாற் கணுக்கு றங்கு
நீடுதோன் முழங்கைக் காற்காம்
மலக்குடற் கட்டு வேர்வை
வாதக்கீல் வாயுவி தாமே.

-சபாபதி கையேடு

It is characterized by excruciating pain and swelling involving knee joints, hip joints, elbow joints, shoulder joints and associated with systemic disturbances like dryness of mouth, pyrexia, headache, palpitation, constipation and sweating. In advanced cases it may affect the heart and produce “Thamaraga vaayu”.

- **IYA KEEL VAAYU:**

கருதருங் கபக்கீல் வாயு
கண்டிடின் உடலிளைக்கும்
உருமெலி வாக்குங் கொள்ளும்
உண்டியைச் சுருக்கு மின்பந்
துருதியில் நீங்கு முட்டிற்
தாங்கொணா வலுவை யாக்கும்
இருமலே விக்கல் வாந்தி
சோபைபாண் டெழுப்பும் பாரே

- சபாபதி கையேடு

It is characterized by severe pain in the joints associated with emaciation of the body, anorexia, insomnia, cough, hiccough, vomiting, anaemia and dropsy. The common sites are spinal cord, hip joints and knee joints.

◈ VALI IYA KEEL VAAYU:

வையம் வாதக் கபக்கீல்
வாயுவான் வலி மிகுந்தே
உயங்குநீர் கோத்து கீல்கள்
ஓரியின் தலைபோற் காணும்
நயங்கொள்ள முடக்கல் நீட்டல்
நண்ணிடா மெய்யுங் காயும்
மயக்குறு முறக்க மின்னாம்
மன்னிய நெரிக்கட் டாமே.

-சபாபதி கையேடு

It is characterized by pain in the joints associated with effusions of joint fluid and swelling, restricted joint movements, pyrexia, fainting, insomnia, especially in knee joint asymmetrically, lymphadenopathy, generalized malaise, atrophy of the affected limb etc. The affected joint looks like “Fox’s Head”

◈ VALI AZHAL KEEL VAYU:

வாத பித்தக் கீல் வாயுவின்
வருங் குறிச் சாற்றக் கேளாய்
யேதமார் மந்த மேப்பம்
இரைச்சலும் வயிற்றில் காணும்
ஒருதுங் குத்தல் வீக்கம்
ஒய்தலில் எரிச்ச லுண்டாம்
காதறு முறக்க மின்மை
காய்ச்சலுங் காணுங் கண்டாய்.

- சபாபதி கையேடு

It is characterized Indigestion,belching, flatulence constipation and increased body weight. Pain and rednesss burning sensation, in wrist , ankle joint, inter phalangeal joints.sleeplessness and fever occurs.

VALI IYA KEELVAYU:

வையம் வாதக் கபக்கீல்
வாயுவான் வலி மிகுந்தே
உயங்குநீர் கோத்து கீல்கள்
ஓரியின் தலை போற் காணும்
நயங்கொள்ள முடக்கல் நீட்டல்
நன்னிடா மெய்யுங் காயும்
மயக்குறு நெறிக்கட் டாமே.

உடலது வெதும்பிக் கை கால்
உடலது கடுத்து நொண்டு
கடலுதாங் கால்க ரங்கள்
கனத்தாற்போ லுயர்ந்து காணும்
சடமது விழுந்த தாகுஞ்
சலங்கெட்டு தோட முண்டாம்
முடமதாங் கைகால் தானும்
முடங்கின வாத மாமே. -சபாபதி கையேடு

It is characterized by Swelling in the both knee joint, pain and pricking sensation in both knee joints, inability to flex and extended upper limb and lower limb. Insomnia, emasiation, lymph adenopathy in axilla, inguinal region, muscular atrophy in affected limbs, swelling of joint resemble fox head.

AZHAL VALI KEEL VAYU

வெயிலிடைத் திரிதல் பித்த
மிகுவுண வருந்த ளுள்ளம்
பயிறு கவலை யாதிப்
பண்பிணால் பித்த வாதம்
கயிலுறு வாய்வு தோன்றிக்
கைப்புடன் மயக்கம் வாந்தி
இயறுபல்லிற் செந்நீர்
இறங்குநால் நோக்குங் கொள்ளும். !

-சபாபதி கையேடு

It is characterized by joint pain and swelling, inability to flex and extend the knee joint associated with rhinitis throat soareness, sneezing, vomiting body pain fever.

AZHAL IYA KEEL VAYU

மிதமிலாக் கலவி யையை
மிகுவிக்கு முண்டி பித்த
கதமுரு செயலி வற்றிற்
காண்பித்தக் கபக்கீல் வாயு
இதமறு மயக்கம் வாந்தி
எரிசுரந்த் தலை நோய் வீக்கம்
மதகரி நனயின் மார்பு
துடிப்புடன் எரிவும் செய்யும். - சபாபதி கையேடு

This type of keelvayu is associated with veneral disease, in prodormal stage the main symptom is sever head ache, nausea, vomiting, fatigue, body ache. Then it aggreviate with high body temperature pain and swelling elbow and knee joint, inability to flewxion and extension, later swelling of the joint appearas like fox head, (it shows its severity.

◈ IYA THEEK KEEL VAYU

ஐயினைப் பெருக்கு முண்டி
யயிலலாற் குளிருங் காற்றால்
மெய்யறு கோழை மிக்கு
மிகுவலி தொண்டை கட்டல்
ஐயுரு காய்ச்சல் வாந்தி
அயர்வுடன் இருமல் வீக்கம்
செய்யுகீல் மடக்கல் நீட்டல்
செய்திடாத் துயருடன் டாமே. - சபாபதி கையேடு

This type of keelvayu is Rhinitis, throat soreness, joint pain and swelling, inability to flex and extend the knee joint associated with rhinitis throat soarness, sneezing, vomiting body pain high body temperature..

◈ MUKKUTRA KEEL VAAYU :

மிக்குற வியர்த்தல் மூச்சு
மேலிட்டல் தலை கிறுத்தல்
மக்கறு மயக்கந் தோன்றல்
வாந்தியே வாய்பிதற்றல்
பொக்கரு மலநீர் கட்டல்
பொருமிய நீக்கங் காணல்
முக்குற்றக் கீலின் வாயு
முகிழ்த்திடுங் குறிக ளாமே ! - சபாபதி கையேடு

It is characterized by Fever , pain, and swelling, swelling increases due to elevated kabam, delirium. if untreated can death occur.

LINE OF TREATMENT

In Siddha system the main aim of the treatment is to cure Udarpini (due to Mukkuttram) and Manapini (due to changes in Mukkunam). Treatment is not only for perfect healing but also for the prevention and rejuvenation.

It is essential to know the disease, the aetiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence must be observed clearly.

Line of treatment is as follows:

1. Kaapu (Prevention)
2. Neekkam (Treatment)
3. Niraivu (Restoration)

Thiruvalluvar details the duty of the physicians, i.e. study the disease, study the cause, seek subsiding ways and do what is proper and effective.

"நோய் நாடி நோய் முதல் நாடி அது தணிக்கும்
வாய் நாடி வாய்ப்பச் செயல்"

"உற்றானளவும் பிணியளவுங் காலமும்
கற்றான் கருதிச் செயல்"

திருக்குறள் (மருந்து)

1)KAPPU (Prevention):

The prevention methods for Azhal keel vaayu are as follows:

- Control the body weight by diet and exercise.
- Modify the nature of work which gives stress to a particular joint.
  e.g. - Avoid prolonged standing and long distance walking.
- Avoid intake excess sour, astringent and bitter tasted foods.

2**) NEEKKAM (Treatment in Siddha):**

The aim of Neekkam is based on

- To bring the deranged Thodams to normal equilibrium state.
- To treat the patient with internal medicine and external medicine.

First the deranged vatham has to be brought to its normal state by giving purgation. It is mentioned in the following verse

“விரேசனத்தால் வாதம் தாழும்

வமனத்தால் பித்தம் தாழும்

நசிய அஞ்சனத்தால் கபம் தாழும்”

-சித்த மருத்துவாங்க சுருக்கம்

1. PURGATIVE:

In Azhal keel vaayu vatha kutram is deranged. So a purgative medicine Agasthiyar kuzhambu - 130 mg with ginger juice was given in early morning in empty stomach on the first day of treatment.

2.INTERNAL MEDICINE:

Sarva noi linga chenduram– 130 mg twice a day given with honey after food.

Ref- Anuboga vaithiya Navaneetham, part 4, pg no 53&54

3. E XTERNAL MEDICINE:

Maasha Thylum [ulunthu thylum]

Ref: Vaithiya Sinthamani (Sigicha Rathina deepam) Pg no:202

C.Kannusamipillai Edition 2007

4.DIET TO BE ADVISED :

- **VEGETABLES** **:**Tender brinjal, Tender drumstick, Lablab bean.
- **LEAVES** :Sessile leaves,Black night shade, Hog weed, Climbing brinjal, dog mustard leaves, Curry leaf.
- **FRUITS** :Pomagranate, apple,Dates palm,country fig, Jambul fruit.
- **NON VEGETARIAN** :Goat, prawn fish. And Advised to take milk

4. DIETARY RESTRICTIONS:

இச்சாபத்தியத்தில் நீக்கும் பொருட்கள்

"கடுகு நற்றிலத் தெண்ணைய் கூழ்ப்பாண்டங்கள் கடலை
வடுவதாகிய தெங்குமா வருக்கை நற்காயம்
மடிவி லாதவெள் ளுள்ளிகொள் புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச் சாபத்தியம்"

சித்த மருத்துவாங்க சுருக்கம்

Mustard, sesame oil. Pumpkin, country arrack, groundnut, coconut, mango, jackfruit,garlic, asofoetida, tobacco, bitter – guard, sesbania leaves, excessive sexual desire.

" புளிதுவர் விஞ்சும் கறியால் பூரிக்கும் வாதம் "

நோய் நாடல் நோய் முதல் நாடல் திரட்டுபாகம்.

Astringent and sour tastes to be avoided.

Modern Aspects

MODERN ASPECTS

OSTEO ARTHRITIS

INTRODUCTION:

Osteoarthritis can be defined as a degenerative, non-inflammatory joint disease characterised by destruction of articular cartilage and formation of new bone at the joint surfaces and margins. However, it is a misnomer and the right term is Osteoarthrosis or degenerative joint disease.

EPIDEMIOLOGY:

Osteoarthritis is by far the most common joint disorder throughout the world, and is one of the leading cause of disability in the elderly. Although the disease commonly affects the cervical and lumbar spine, most epidemiologic studies report that it has a predilection for weight bearing joints in the leg and certain joints in the hand.

The prevalence of osteoarthritis in all joints correlates strikingly with age .One third of people aged 65 years and older have knee osteoarthritis that is evident by radiograph. Before the age 50, men are more likely to have osteoarthritis than women, but after age 50,it is common in women who are more likely to be affected.

Osteoarthritis is already one of the ten most disabling diseases in developed countries.

- Farming 1-9 years increases the risk of osteoarthritis 4 times, farming 10 or more years increases the risk 9 times.
- World wise estimates are that 10% of men and 18% of women aged over 60 years have symptomatic osteoarthritis.
- 80% of those with osteoarthritis will have limitations in movement, and 25% cannot perform their major daily activities of life.

ANATOMY OF THE KNEE JOINT

Introduction:

The knee joint is the largest and most complex joint of the body. The complexity is the result of fusion of three joints in one. It is formed by fusion of the lateral femorotibial, medial femorotibial and femoropatellar joints.

Injuries to the knee joint are amongest the most common in sporting activities and understanding the anatomy of the joint is fundamental in understanding any subsequent pathology in the joint.

Type:

It is compound synovial joint, incorporating two condylar joints between the condyles of the femur and tibia, and one saddle joint between the femur and patella

Articular surfaces

The knee joint is formed by

- The condyles of the femur
- The condyles of the tibia and
- The patella

The femoral condyles articulate with the tibial condyles below and behind, and with the patella in front.

Ligaments

The knee joint is supported by a number of ligaments that are,

- Fibrous (articular) capsule
- Ligamentum patellae
- Tibial collateral(medial) ligament
- Fibular collateral ligament
- Oblique popliteal ligament
- Arcuate popliteal ligament

- Cruciate ligaments
- Menisci(semilunar cartilages)
- Transverse ligament

The stability of the knee owes greatly to the presence of its ligaments. Each has a particular function in helping to maintain optimal knee stability in a variety of different positions.

The knee joint capsule:

The joint capsule is a thick ligamentous structure that surrounds the entire knee. Inside this capsule is a specialized membrane known as the synovial membrane which provides nourishment to all the surrounding structures. Other structures include the infrapatellar fat pad and bursa which function as cushions to exterior forces on the knee. The capsule itself is strengthened by the surrounding ligaments.

Menisci (semi lunar cartilages)

The menisci are two fibro cartilaginous discs.They are shaped like crescents. They deepen the articular surfaces of the condyles of the tibia and partially divide the joint cavity into the upper and lower compartments.

Functions of menisci

- They help to make the articular surfaces more congruent
- The menisci serve as shock absorbers
- They help to lubricate the joint cavity

Because of their nerve supply, they also have a sensory function. They give rise to proprioceptive impulses.

Synovial fluid

Synovial fluid is a thick, stringy fluid found in the cavities of synovial joints.With its egg like consistency(synovial comes from latin for “egg”), synovial fluid reduces friction between the articular cartilage and other tissues in joints to lubricate and cushion them during movements.

Muscle groups surrounding the knee joint:

The two main muscle groups of the knee joint are the quadriceps and the hamstrings. Both play a vital role, both moving and stabilizing the knee joint.

Quadriceps muscle:

The quadriceps muscle group is made up of four different individual muscles which join together forming the quadriceps tendon. This thick tendon connects the muscle to the patella which in turn connects to the tibia via the patellar tendon. Contraction of the quadriceps, pull the patella upwards and leads to knee extension.

Hamstrings muscle:

The Hamstrings muscle function is flexing the knee joint as well as providing stability on either side of the joint line.

Movement

- Flexion
- Extension
- Medial rotation
- Lateral rotation

Flexion and extension are the chief movements. Those take place in the upper compartment of the joint above the menisci.

Rotatory movements at the knee are of a small range. Rotations take place around a vertical axis, and are permitted in the lower compartment of the joint, below the menisci.

Blood supply:

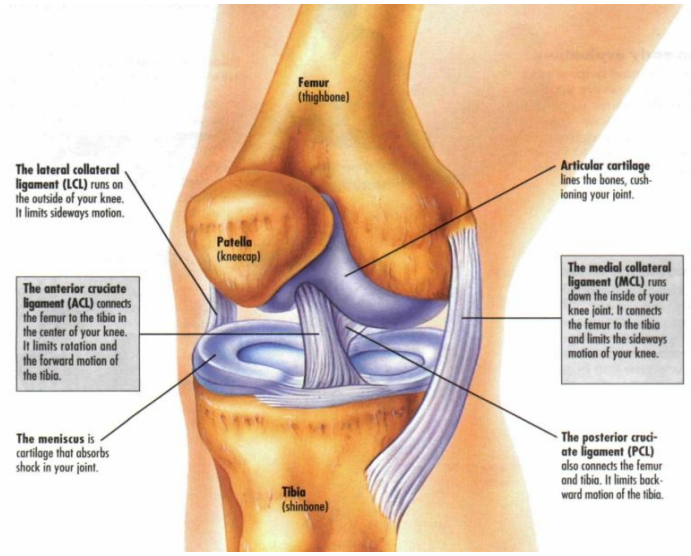
The knee joint is supplied by the anastomosis around it. The chief sources are

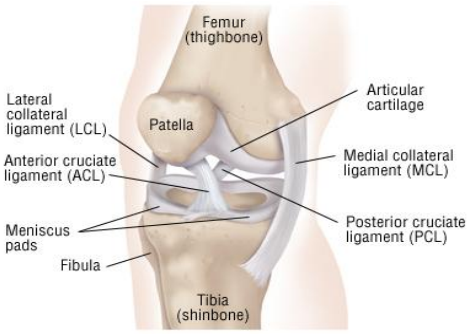
- Five genicular branches of the popliteal artery
- The descending genicular branch of the femoral artery
- The descending branch of the lateral circumflex femoral artery
- Two recurrent branches of the anterior tibial artery
- The circumflex fibular branch of the posterior tibial artery

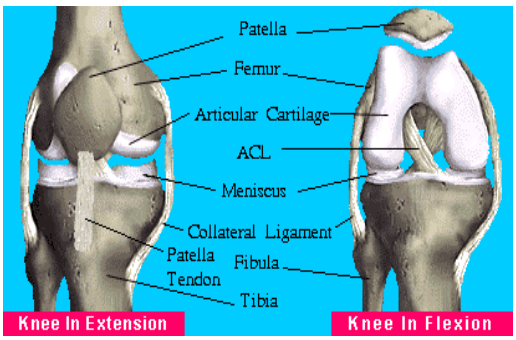
Nerve supply

- Femoral nerve
- Sciatic nerve
- Obturator nerve

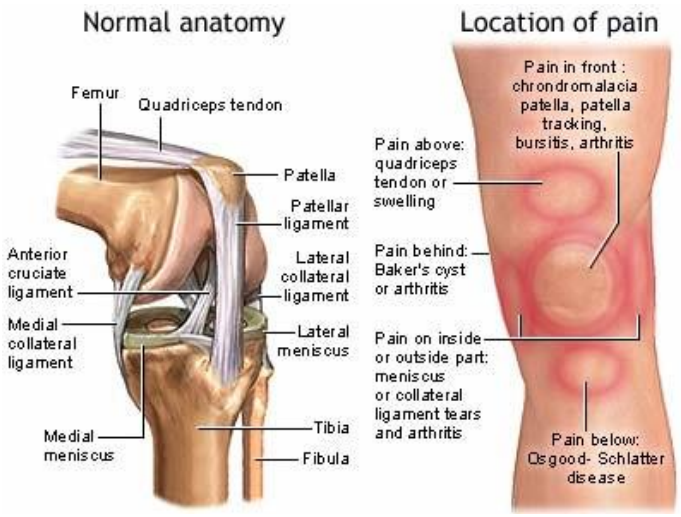
LIGAMENTS OF THE KNEE JOINT



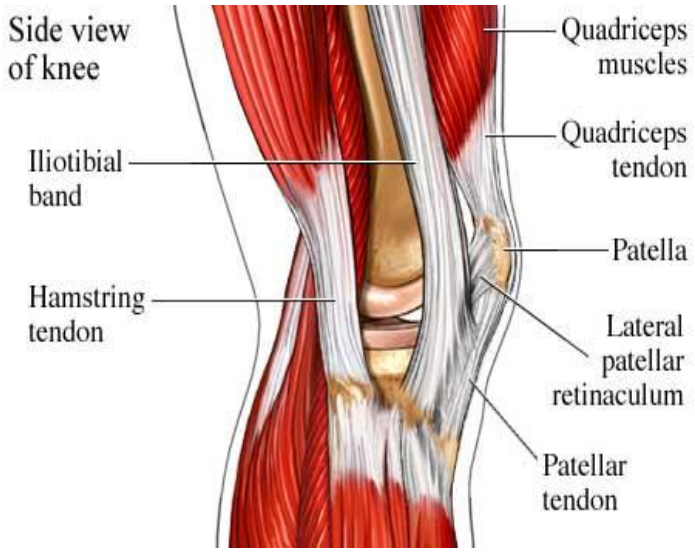




LOCATION OF PAIN



MUSCLES OF THE KNEE



AETIOLOGY:

PRIMARY CAUSE OF OSTEOARTHRITIS:

Though exact cause is not known, the following factors are suspected to play an important role in the causation of primary osteoarthritis

1) Endocrine
2) Post Traumatic
3) Inflammatory joint disease
4) Metabolic
5) Congenital or developmental
6) Genetic
7) Neuropathic and others

1. ENDOCRINE:

People with Diabetes may be prone to osteoarthritis. Other endocrine problems also may promote development, including Acromegaly, Hypothyroidism, Hyper parathyroidism and Obesity.

2. POST TRAUMATIC:

Traumatic causes can be further divided into macro trauma or micro trauma. An example of macro trauma is an injury to the joint such as bone break causing the bones to line up improperly (mal alignment), lose of stability or damage cartilage. Micro trauma may occur over time (chronically). An example of this would be repetitive movements or the overuse noted in several occupations.

3. INFLAMMATORY JOINT DISEASE:

This category would include infected joints, chronic gouty arthritis and rheumatoid disease.

4. METABOLIC:

Disease causing errors of metabolism may cause osteoarthritis. Examples include Paget's disease and Wilson's disease.

5. CONGENITAL OR DEVELOPMENTAL:

Abnormal anatomy such as unequal length of legs may be a cause of osteoarthritis.

6. GENETIC:

A genetic defect may promote breakdown of the protective architecture of cartilage. Examples include collagen disturbances such as Ehlers- Danlos Syndrome.

7. NEUROPATHIC:

Diseases such as Diabetes can cause nerve problems. It may affect the the Joints and limbs.

8. OTHERS:

Nutritional problems may cause osteoarthritis. Other disease such as haemophilia and sickle cell anaemia are further examples.

SECONDARY CAUSES OF OSTEO ARTHRITIS:

The causes for secondary osteoarthritis of the knee are as follows:

- Obesity
- Valgus and varus deformities of the knee.
- Intra – articular fractures of the knee, etc.
- Rheumatoid arthritis, infection, trauma, TB, etc.
- Hyper parathyroidism.
- Haemophilia.
- Syringomyelia
- Overuse of intra- articular steroid therapy.

It is generally observed that secondary osteoarthritis occurs in the younger age groups and is more severe than the primary. Apart from all the features of osteoarthritis, secondary osteoarthritis has the features of the corresponding aetiological condition.

CLASSIFICATIONS:

It could be divided into 2 types

1. Primary or idiopathic osteoarthritis
2. Secondary osteoarthritis

Primary osteo arthritis results from changes caused by specific inflammatory or metabolic conditions while secondary osteo arthritis is caused by other conditions that damage cartilage.

PATHOGENESIS:

PRIMARY OSTEOARTHRITIS	**SECONDARY OSTEOARTHRITIS**
1.Usually limited to one or a small number of joints.	May be limited to a small number of joints if injury related or may be in joints throughout body, if disease related
2.No specific inflammatory or metabolic condition known to be associated with arthritis is present.	Condition that cause damage to cartilage are present, such as - ◈ Inherited disease of iron, calcium or copper storage such as haemochromatosis, Hyperparathyroidism or Wilson's disease. ◈ Neurologic disorder that result in the loss of nerve function. ◈ Congenital disease that cause an imbalance in the joints.
3.No history of specific injury or trauma.	History of injury to joints, such as fractures and tears or history of trauma to joints, such as repetitive heavy lifting.

NORMAL ARTICULAR CARTILAGE:

Normal cartilage has two main components. One is the extra cellular matrix, which is rich in collagens (mainly types II, IX and XI) and proteoglycans IX mainly aggrecan. Aggrecan is a central core protein bearing numerous glycosaminoglycans chains of chondroitin sulphate and keratin sulphate, all capable of retaining water.

The second component consists of isolated chondrocytes, which lie in the matrix. The matrix component is responsible for the tensile strength and resistance to mechanical loading of the articular cartilage.

PASSAGE OF NORMAL CARTILAGE TO AGING CARTILAGE:

Several structural and biochemical changes involving the non collagenous component of the matrix occur during aging. These changes alter biochemical properties of the cartilage that are essential for the distribution of forces in the weight bearing zone.

Glycosamino glycans are modified qualitatively, they become shorter as the cartilage ages.The concentration of type VI keratin sulphate increase during aging, to the determent of type IV keratin sulphate.

These quantitative and qualitative changes in proteoglycan reduce the capacity of the molecules to retain water. Thus aging cartilage contains less water, which alters the biochemical properties of the cartilage.

OSTEOARTHRITIC JOINTS

Osteoarthritic joints have abnormal cartilage and bone, with synovial and capsular lesions.

Macroscopically the most characteristic elements are,

- Reduced joint space.
- Formation of osteophytes(protrusion of bone and cartilage) mostly at the margins of joints.
- Sclerosis of the subchondral bone

SIGNS AND SYMPTOMS:

The most common signs and symptoms of osteoarthritis are;

- Predominant symptom is pain which decreases on walking. The pain is poorly localised and dull aching in nature.
- The patient complains of early morning stiffness which subsides over the day after activity.
- Morning stiffness, which usually lasts no more than 30 minutes.
- Swelling of the joints
- Minimal tenderness
- Restricted range of joint movements
- Coarse crepitus can be elicited

SITES:

Common sites of primary osteoarthritis:

- Apophyseal joint of the cervical spine
- Thoraco lumbar spine
- First carpometacarpal joint
- Distal interphalangeal joint
- Patella femoral joint
- Tibio femoral joint
- First metatarsalphalangeal joint

Intermediate sites:

- Acromio clavicular joint
- Hip joint

Uncommon sites:

- Shoulder joint
- Elbow joint
- Wrist joint
- Metaphalangeal joint
- Ankle joint

DIAGNOSTIC CRITERIA:

Formal criteria helpful for diagnosis of osteoarthritis in synovial joints:

- Age greater than 60 years.
- Pain and swelling in knee joint
- Morning stiffness lasting less than 30 minutes.
- Crackling sensation (crepitus) present in knee joint.
- Joint- line or periarticular tenderness.
- Bony swelling (osteophyte) around joint margins.
- Restricted joint movements

DIAGNOSIS:

There is no single sign, symptom or test result that allows a definitive diagnosis of osteoarthritis. Instead the diagnosis is based on a consideration of several factors, including the presence of the characteristic signs and symptoms of osteoarthritis, physical examination and the results of laboratory tests and x-rays.

COMPLICATIONS OF OSTEOARTHRITIS:

The major complications of osteoarthritis of knee

- Joint deformities
- Subluxation
- Ankylosis
- Intra- articular loose bodies

Life style effects include

- Depression
- Anxiety
- Feelings of helplessness
- Limitation of daily activities
- Job limitations

PROPERTIES OF TRIAL DRUGS

இலிங்கம் - NATURAL RED SULPHIDE OF MERCURY (Cinnabar)

Potency- Hot

Action - உடல் தேற்றி (Alterative)

General Properties

"பேதிசுரஞ் சன்னி பெருவிரண நீரோடுத
காதகடி காசங் கரப்பான்புண் - ணோத
வுருவிலிங்க சங்கதமா யூறுகட்டி யும்போங்
குருவிலிங்க சங்கமத்தைக் கொள் "
"ஆதி யிரதவுருக் காதலாற் சாதிலிங்க
மோதி லிரதகுண முற்றுடலிற் - றீதுபுரி
குட்டங் கிரந்தி கொடுஞ்சூலை வாதமுத
லுட்டங்கு நோய்களையோட் டும் "

- குணபாட தாது ஜீவ வகுப்பு

Uses:

It cures diarrhoea, pyrexia, delirium, urticaria, tuberculosis, scabies, insect bites, syphilis, skin diseases, throbbing pain(soolai) and vatha diseases.

வெங்காரம்- SODIUM BIBORATE

Action:

- Refrigerant
- Diuretic
- Emmenagogue
- Lithontriptic
- Antiseptic

Taste: Sweet With Astringent

General Properties

சொறிபுடையெண் குன்மநமை சோரி யாசம்
பறிகிரகணி கல்லூனம் பன்னோய்-நெறியைத்
தடங்கணங்க பங்கிருமி சர்ப்பவிடஞ் சந்நி
யிடங்கணங்க லக்கிற்போ மெண்.

- குணபாட தாது ஜீவ வகுப்பு

Vengaram is indicated for eight type of ulcers, dental diseases, urinary tract infections, kabha disorders, delirium.

உளுந்து

Botanical name: Vigna mungo (Linn) hepper

Family: Fabaceae

Part used : Seed, root

Organo leptic characters

Taste : sweet

Potency: cold

Division : sweet

Action :

- Demulcent
- Refrigerant
- Aphrodisiac
- Galactagogue
- Nervine tonic
- Nutritive

General Properties

செய்ய உளுந் திற்குச் சிலேத்மவனி லற்பிறக்கும்
வெய்யபித்தம் போமந்தம் வீறுங்காண் - மெய்யதனில்\
என்புருக்கி தீரும் இடுப்புக் கடுபலமாம்
முன்பு விருத்தியுண்டாய் முன்.

(அகத்தியர் குணவாகடம்)

It gives strength to the waist of women,it acts as good nutrient and refrigerant to body.

Chemical constituents:

Black gram contains tryptophan, methionine and leaves contain saponin.

சிற்றாமுட்டி

Botanical name: Pavonia zeylanica.Cav

Family : Malvaceae

Part used : Samoolam (whole plant)

Organoleptic characters :

Taste : Pungent

Potency : Cold

Division : Sweet

General Properties

அத்தி சுரமுதல் அனந்த சுரம் பித்தமும் போம்
மெத்த விழிக்கொளியாம் வீறுதயி - லத்திற்காம்
நற்றா மரைத்திருவு நாடு மெழிற்றிருவே !
சிற்றாமுட் டித்துரைச் செப்பு.

- அகத்தியர் குணவாகடம்

It is indicated for osteomyelitis, pitha disorders, febrile conditions.

Chemical constituents:

Ephedrine and pseudoephedrine constitute the major alkaloids from the aerial parts of the plant, which also show traces of sitosterol and palmitic, stearic and hexacosanoic acids. The flavones: 5,7-dihydroxy-3-isoprenyl flavone (1) and 5-hydroxy-3-isoprenyl flavone (2), β-sitosterol and stigmasterol have been isolated from the plant. The analgesic alkaloid (5′-Hydroxymethyl-1′-(1,2,3,9-tetrahydro-pyrrolo [2,1-b] quinazolin-1-yl)-heptan-1-one) has also been found.

RICINUS COMMUNIS

ஏரண்டம் - General Properties

வாதத் தொடக்கை வரவொட்டா மற்படிக்குக்
காதத்துக் கப்பாற் கடியுமே- சூதத்தைப்
பேரண்டப் பந்திக்கும் பேதிக்கு நோய்க்காட்டை
யேரடண்ட மென்பதினையே

- தேரன் வெண்பா

ஆமணக்கு வேர்

Botanical name: Ricinus communis

Family : Euphorbiaceae

Part used : Root , leaf seed.

Organoleptic characters :

Taste : bitter

Potency : hot

Division : pungent

Action :

வாதமடக்கி - Anti vaatha.

The Root of Ricinus communis is used as an important ingredient inall anti vatha decocotion and anti vatha oil preparations like vathanth thylum, poothika thylum, chukka thylum.

Chemical constituents :

Ricintriglyceride, stigmasterol,ricinine,gallic acid,aleuritic acid,ethyl brevifolincarboxylate,9-hydroxytridecyl docosanoate, lupeol,luteolin ,palmitic acid,octacosanol,and octadecane .

அதிவிடயம்

Botanical name: Aconitum heterophyllum

Family: Ranunculaceae

Part used : Root

General Properties

அதிவி டயம் சர்க்க ராற்புதநோய் வெப்பு
கொதிமருவு பேதியொடு கோழை - எதிர்வாந்தி
என்றுரைக்கும் நோய்க்கூட்டம் இல்லா தகற்றிவிடும்
குன்றை நிகர்முலையாய் ! கூறு.

- அகத்தியர் குணவாகடம்

It is indicated for intermittent fever , diarrhoea, cough, vomitting

Organoleptic characters :

Taste : Bitter

Potency : hot

Division : pungent

Action :

- பசித்திதூண்டி - Stomachic
- துவர்ப்பி - Astringent
- ஆண்மைபெருக்கி- Aphrodiasic
- உரமாக்கி - Tonic
- முறைவெப்பகற்றி -Antiperiodic
- வெப்பகற்றி - febrifuge

Chemical Constituents:

Atisine hetisine, heterophyllinine, Heterophylidine, hetidine, atidine, pseudo aconitine.

சிற்றரத்தை

Botanical name: Alpnia galanga

Family : Zingeberaceae

Part used : Root

Organoleptic characters :

Taste : pungent

Potency : hot

Division : pungent

Action :

- கோழையகற்றி - Expectorant
- வெப்பகற்றி - Febrifuge
- பசித்திதூண்டி - Stomachic

General Properties

வாதபித் தங்கரப்பான் வாதஞ் சிரோரோகஞ்
சேர்ந்தகப முத்தோடஞ் சீதமொடு - நேர்ந்தசுரம்
மற்றரத்தைக் காட்டி வருமிரும லுந்தீரும்
சிற்றத்தை வன்மருந்தால் தேர்.

- தேரன் குணவாகடம்

Vatha diseases, eczema, head ache, cough,cold, febrile conditions, and kabha diseases were indicqated for alpinai galangal.

Chemical constituents:

Root contains campheride, galangin and alpinin. Rhizome contains volatile essential oil, it has 48% of methyl cinnamate, 20-30 cincole, camphor and alpha – pinene.

சிறுகாஞ்சொறிவேர்

Botanical name: Tragia involucrata

Family : Euphorbiaceae

Part used : Root

Organoleptic characters :

Taste :Bitter

Potency : hot

Division : pungent

General Properties

சிறுகாஞ் சொறிவேர் சிலேத்துமசுவா சத்தைக்
குறியாத முச்சுரக் குழாத்தைச் - சொறியுங்
கரப்பான் சிறுசிரங்கை காலைத்தா கத்தை
உரப்பாகச் சாடுமென வோது.

- அகத்தியர் குணவாகடம்

Siru kanchori root indicated for Cardiac asthma. Fever due to all three humours derangements, eczema, scabies, vatha, thirst.

இந்துப்பு - Impura Sodium Chloridium

Action :

Laxative

Diuretic

Carminative

Stomachic

General Properties

அட்டகுன்மம் மந்தம் அசிர்க்கரஞ்சூர் சீதபித்தந்
துட்டவையம் நாடிப்புண் டோடங்கள் - கெட்டமலக்
கட்டுவிட விந்தையக் காமியநோய் வன்கரப்பான்
விட்டுவிட விந்துப்பை விள்.

சென்னிக்கண்ணா பற்றூர் செவிகவுள்கண் டம்பகநோய்
சந்நியா சங்காசந் தாகமிரைப் - புன்னிரத்த
மூலஞ் சிலந்திநளி மூடிகநஞ் சூதை வலி
சூலஞ் சிதையுமிந்தாற் சொல்.

- குணபாட தாது ஜீவ வகுப்பு

Eight type of ulcers, derangemants of three humours and vatha discomfortrs, delirium, thirst, dysponea, painful conditions,

தண்ணீர்விட்டான் கிழங்கு

Botanical name: Asparagus racemosus

Family : Alliaceae

Part used : Leaf, Tuber

Organoleptic characters :

Taste : Pungent

Potency : Hot

Division : Pungent

Action :

- உடலுரமாக்கி - Nutritive
- உள்ளழலாற்றி - Demulcent
- பாற்பெருக்கி - Galactogouge
- காமம்பெருக்கி - Aphrodisiac
- இசிவகற்றி - Antispasmodic

General Properties

நீரிழிவை போக்குந் நெடுநாட்சு ரத்தையெலாம்
ஊரைவிடுத் தோடவு ரைக்குங் காண்- நாரியரே! ஆ
வெண்ணீர்பெய் சோமநோய் வெட்டை யனந்தனிக்குந்
தண்ணீர்விட் டான்கிழங்கு தான்.

- அகத்தியர் குணவாகடம்

Thanneer vittan kizangku is indicated for Diabetes, chronic fever, rickets, sexually transmitted diseases.

Chemical constituents:

It contains saachrine, mucilage and Asparagamine.

Materials and Methods

PRECLINICAL

STUDY

Form B (per rule 8(a)

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to sent either to the CPCSEA (address in form A above) or Institutional Animal Ethics Committee (IAEC)

Part A

*1. **Name and address of establishment :**

National Institute of Siddha,
Tambaram Sanatorium,
Chennai- 47.

***2. Registration number and date of registration**

1248/ac/09/CPCSEA

3. Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C

King Institute, Guindy, Chennai

4. Place where the animals are presently kept (or proposed to be kept)

Animal house, NIS

5. Place where the experiment is to be performed (Please provide CPCSEA Reg.Num)

Pharmacology Laboratory, NIS. 1248/ac/09/CPCSA

6. Date on which the experiment is to commence and duration of experiment

February - 2012, 6 months

7. Type of research involved (Basic Research/Educational/Regulatory)

M.D Dissertation

Signature

Date:

Place: **Name and designation of Investigator**

***Applicable only for application to be submitted to CPCSEA**

PART B

Protocol form for research proposals to be submitted to the committee/Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

1. Project / Dissertation / Thesis Title:

Pre clinical and clinical study on AZHAL KEEL VAYU (OSTEO ARTHRITIS) and the drug of choice is SARVA NOI LINGA CHENDURAM (int) & MAASHA THYLUM(ext)

2. Principal Investigator / Research Scholar / Research Guide / Advisor

Guide

a. Name Prof. Dr.K.Manickavasakam MD (S).,

b. Designation Head of the department and Director i/c of NIS

c. Dept / Div/ Lab Dept of Maruthuvam

d. Telephone No. 9444249798

e. Experience 26 years

3. List of names of all individuals authorized to conduct procedures under this proposal

a. Name
b. Address
c. Experience
Research Scholar:
a. Name: Dr R.RADHA KRISHNAN
b. Address: 2nd yr , Dept of Maruthuvam,
National Institute of Siddha,
Chennai -47.

4. Funding source with complete address (Please attach the proof)

Self

5. Duration of the project

a. Number of months **:** Three months

b. Date of initiation(Proposed) **:** February, 2012

c. Date of completion (Proposed) **:** August, 2012

6. Detailed study plan may be given (Not more than one page)

Enclosure 1

7. Animals required

a. Species/Common name : Rat, Mice

b. Age / weight / size : 6 weeks. Rat-150-200gms, Mice-20-25 gms.

c. Gender: Both

d. Number to be used (Year-wise breakups and total figures needed to be given)
Mice: 20
Rats: 40

Acute toxicity (WHO guidelines, 1993)

S.No	Group	No of mice
1	Vehicle control (radish juice)	10 (5 male, 5 female)
2	Toxic dose (10X therapeutic dose) (Single dose) (2.34mg)	10 (5 male, 5 female)

Sub acute toxicity studies : 3 months

S.No	Group	No of Rats
1	Vehicle control (Radish juice)	10 (5 male, 5 female)
2	1XTherapeutic dose(2.34mg)	10 (5 male, 5 female)
3	5XTherapeutic dose(11.7mg)	10 (5 male, 5 female)
4	10XTherapeutic dose(23.4mg)	10 (5 male, 5 female)

e. Number of days each animal will be housed: 1 week

8. Rationale for animal usage

a. Why is animal usage necessary for these studies?

Preclinical toxicity studies are generally carried out using animal models. So animals are required to conduct toxicity studies.

b. Why are the particular species selected required?

Standard protocols recommends the use of rodents for the toxicity studies.

c. Why is the estimated number of animals essential?

The recommended guidelines requires the estimated number of animals

d. Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.

No

e. If yes, why new experiment is required?

Not applicable

f. Have similar experiments been made by any other organization agency? If so, their results in your knowledge.

NO

9. Description the procedures to be used.
List and describe all invasive and potentially stress full non-invasive procedures that animals will be subjected to in the course of the experiments.

Furnish details of injections schedule

Substances:
Doses : Enclosure 2
Sites :
Volumes :
Blood withdrawal
Volumes:
Sites :
Radiation (dosage and schedules):

10. Please provide brief descriptions of similar studies from invitro / invivo (from other animal models) on same/similar test component or line of research. If,enough information is available, justify the proposed reasons.

Not applicable

11. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification

Not applicable

12. Will survival surgery be done?

Not applicable

If Yes, the following to be described.

a. List and description of all such surgical procedures (including methods of asepsis)

Not applicable

b. Names, qualifications and experience levels of operators

Not applicable

c. Description of post-operative care

Not applicable

d. Justification if major survival surgery is to be performed more than once on a single individual animal.

Not applicable

13. Methods of disposal post-experimentation

a. Euthanasia (Specific method):

Excessive anaesthesia

b. Method of carcass disposal:

Carcass will be packed in bio-hazardous bag and disposed through G.J.Multi clave private limited, GST road, Tambaram sanatorium, Chennai-47.

c. Rehabilitation: --------

14. Animal transportation methods if extra-institutional transport is envisaged

Air conditioned vehicle

15. Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified)

(a) Radionuclides

(b) Microorganisms / Biological infectious Agents

(c) Hazardous chemicals or drugs

(d) Recombinant DNA

(e) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.

Not applicable

Investigator's declaration.

1. I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previously reported research.

2. I certify that, I am qualified and have experience in the experimentation on animals.

3. For procedures listed under item 11, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.

4. I will obtain approval from the IAEC/CPCSEA before initiating any significant changes in this study.

5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body (to be named).

6. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).

7. I shall maintain all the records as per format (Form D)
8. I certify that, I will not initiate the study unless approval from CPCSEA received in wiring. Further, I certify that I will follow the recommendations of CPCSEA.

9. I certify that I will ensure the rehabilitation policies are adopted.

Signature

Date: **Name of Investigator**

CERTIFICATE

This is certify that the project title……..
……
…..has been approved by the IAEC.

Name of Chairman/Member Secretary IAEC: **Name of CPCSEA nominee:**

Signature with date

Chairman/Member Secretary of IAEC: **CPCSEA nominee:**

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

Enclosure1

SARVA NOI LINGA CHENDURAM (int) (Anuboga Vaithiya Navaneetham Part IV) and maasha thylum Vaithiya Sinthamani - Sigicha Rathina deepam is practiced in siddha system of medicine for Azhal Keel vayu (sabapahti kaiyedu and siddha maruthuvam pothu) is one of the 10 types of keelvayu which is correlate with osteo arthritis (DAVIDSON'S PRINCIPLES & PRACTICE OF MEDICINE, 2002) having the symptoms of Pain and swelling knee joints, morning stiffness& restricted movements in the all joints especially knee joints, body pain, fatigue, dryness of the tongue, Fever, Difficulty in walking etc.

When reviewing literature so for no scientific evaluation were carried out for its toxicity pre-clinically .So in our present investigation we aimed to conduct acute and long term toxicity studies.

Acute and long term study are designed as per WHO guidelines, because WHO has specially given the guidelines for conducting toxicity studies for Traditional medicine.

According to WHO "Traditional Medicine includes a plant derived material or preparation with therapeutic or other human health benefits which contains either raw or processed ingredients from one or more plants .In some traditions, materials of inorganic or animal origin may also be present".

The trial drug is clinically prescribed for 48 days. Hence long term study is designed for 3 months as per WHO guidelines for traditional medicine.

Enclosure: 2
Acute toxicity (WHO guidelines, 1993)

S.No	Group	No of mice
1	Vehicle control (raddish juice)	10 (5 male, 5 female)
2	Toxic dose (10X therapeutic dose) (Single dose) (23.4mg)	10 (5 male, 5 female)

The animals will be monitored for behavioral parameters like alertness, visual placing, stereotypy, passivity, grooming, restlessness, irritability, fearfulness, spontaneous activity, reactivity, touch response, pain response for the first 4 hours after drug administration. Body weight of the animal will be monitored at weekly interval. The animals will be monitored for mortality for 14 days. The animals that die within this period will be subjected to necropsy. All animals will be weighed and sacrificed on the 15^{th} day after administration and then the vital organs including heart, lungs, livers, kidneys, sex organs and brain will be grossly examined.

Sub acute toxicity studies:

S.No	Group	No of Rats
1	Vehicle control (radish juice)	10 (5 male, 5 female)
2	1XTherapeutic dose(2.34mg)	10 (5 male, 5 female)
3	5XTherapeutic dose(11.7mg)	10 (5 male, 5 female)
4	10XTherapeutic dose(23.4mg)	10 (5 male, 5 female)

.

Duration of drug administration : 3 months

All rats were observed for apparent signs of toxicity or behavioral alterations during the experimental period. At the end of each experiment, the rats were fasted 12 hours and then anesthetized with ether. Blood will be collected from a Jugular vein for hematological study. The serum will be separated and the levels of glucose, blood urea nitrogen (BUN), creatinine, total protein, albumin, total bilirubin, direct bilirubin, alkaline phosphatase (ALP), serum glutamate, oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT) will be measured. After the blood collection, the animals were sacrified for tissue examinations. The following organs will be weighed, examined and then fixed in 10% buffered formaldehyde solution for histopathological observations: heart, lungs, livers, kidneys, stomach, brain and sex organs.

For IAEC/CPCSEA usage)

Proposal number:

Date first received :

Date received after modification (if any) :

Approval date :

Expiry date :

Name of Chairman /Member Secretary IAEC : **Name of CPCSEA nominee:**

Signature with date :

Chairman /Member Secretary IAEC: **CPCSEA nominee:**

CLINICAL STUDY

MATERIALS AND METHODS

Title:

Preclinical and Clinical study on **AZHAL KEELVAYU (OSTEOARTHRITIS)** and the drug of choice is **SARVA NOI LINGA CHENDURAM (Internal) & MAASHA THYLAM [ulunthu thylum] (External).**

OBJECTIVE :

Primary objective :

To evaluate the therapeutic efficacy of siddha formulations SARVA NOI LINGA CHENDURAM (Internal) &Mashaa thylum[ulunthu thylum] (External) for reducing pain in the treatment of AZHAL KEEL VAYU (OSTEOARTHRITIS).

Secondary objective:

To evaluate the safety profile (Acute, long term toxicity studies) of this drug.

To study the siddha cofactors such as age, sex, dietary influence.

STUDY DESIGN & CONDUCT OF STUDY.

Study type : An open clnical tial

Study place : OPD and IPD of Ayothidass pandithar hospital, National Institute of siddha, Tambaram sanatorium, Chennai-47.

Study period : 12 months

Sample size : 40 patients

TREATMENT:

MEDICINE NAME :

1. SARVA NOI LINGA CHENDURAM(internal) (5)

Ref : Anuboga Vaithiya Navaneetham , Part 4,

Hackim PA. Mohammed Abdullah Sayubu , Edition: pg no 52 &53

2. MAASHA THYLUM [ulunthu thylum] (external) (6)

Ref: Vaithiya Sinthamani (Sigicha Rathina deepam) Pg no:202

C.Kannusamipillai Edition 2007

DOSAGE : 130 mgs twice a day.

METHOD OF DRUG ADMINISTRATION:

Given for 7 days followed by a break of 5 days. Again the medicine is given for 7 days followed by a break of 5 days. Likewise two more times are repeated.

ADJUVANT: Honey (after food)

COURSE: 48 days

DURATION OF TREATMENT: 28 days

DIET RESTRICTION:

Every first day of break(redieting) starts with head bath with the paste of Ajowan seeds and cow's milk and diet free of salt, tamarind ,etc noted in the form IV D (Dietary advice form). Dietary advice is strictly followed during the period of drug administration as well as redieting period. During redieting period roasted salt intake is recommended.

MAASHA THYLUM (External)

DOSAGE: Sufficient quantity 50 ml

Applied externally over the affected parts.

SUBJECT SELECTION

As and when patients reporting at OPD of Ayothidass Pandithar Hospital with symptoms of inclusion criteria will be subjected to screening test and documented using screening proforma .

INCLUSION CRITERIA

- Age :30-60Yrs
- Sex – Both sex
- Signs and Symptoms of pain ,swelling of knee joints, stiffness & restricted movements
- Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/her own conscious discretion.
- Patients who are willing to take radiological investigation (X RAY KNEE JOINT) and provide blood for lab investigation.

EXCLUSION CRITERIA

- Rheumatoid arthritis
- Gouty arthritis
- Fractures
- Tuberculosis
- Diabetes mellitus
- Hypertension
- Viral fever (Chikun gunya)
- Any other serious illness.
- Cardiac disease
- Renal disease
- Patients taking any NSAID
- Trauma

WITHDRAWAL CRITERIA

- Intolerance to the drug & development of adverse reactions during drug trial.
- Poor patient compliance & defaulters.
- Patient turned unwilling to continue in the course of clinical trial.
- Increase in severity of symptoms

TEST & ASSESSMENTS

A. CLINICAL ASSESSMENT

SIDDHA ASSESSMENT

B. ROUTINE INVESTIGATION

C. SPECIFIC INVESTIGATION

CLINICAL ASSESSMENT(12)

1. Pain of knee joints(Left/Right/Both]
2. Swelling of knee joints
3. Warmth over the knee joints.
4. Stiffness of the knee joints.
5. Crepitations of the knee joints
6. Instability of the knee joints.
7. Joint deformity
8. Restricted movements of the knee joints
9. Muscle weakness, wasting over the knee joint.

SIDDHA ASSESSMENT

1.Thinai :

- Kurinchi (hill areas)
- Mullai (forest)
- Marutham (fertile land)
- Neidhal (coastal area)
- Palai (desert)

2. Paruva Kalam (season)

- Karkaalam
- Koothir kaalm
- Munpanikaalm
- Pinpani kaalam
- Ilavenil kaalam
- Muthuvenil kaalam

3. Poripulankal:

- Mei (Skin etc)
- Vaai (Tongue etc)
- Kan (Eye etc)
- Mooku (Nose etc)
- Sevi (Ear etc)

4.Kanmedriyamand Gnanenthiriyam:

- Vaai (Buccal cavity)
- Kaal (Lower limbs)
- Kai (Upper limbs)
- Eruvaai (Anorectal region)
- Karuvaai (Uro-genital region)

5. **Ezhu Udalkattugal:**

- Saram
- Senneer
- Uoon
- Kozhuppu
- Enbu
- Moolai
- Sukkilam /suronitham

6.Ennvagaithervu (Eight types of Examination):

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
  - Neerkuri
  - Neiku

SIDDHA PARAMETERS

Malam

Moothiram

B . ROUTINE INVESTIGATION

- Hb(gm/dl)
- Total WBC Count(cells/cumm)
- DC- Polymorphs(%)
- Lymphocytes(%)
- Eosinophils (%)
- Monocytes (%)
- Basophils(%)
- Total RBC count million cells/cumm)
- ESR(Men 6-12mm/hr Women 7-18 mm/hr)
- B.glucose (mg/dl)

LIPID PROFILE

- Serum cholesterol(mg/dl)-
- HDL cholesterol(mg/dl)-
- LDL cholesterol(mg/dl)-
- VLDL cholesterol(mg/dl)-
- Serum triglycerides (mg/dl)-

KIDNEY FUNCTION TEST

- B.urea(mg/dl)
- S. total creatinine (mg/dl)

LIVER FUNCTION TEST

- S.total bilirubin(mg/dl)
- S.direct bilirubin (mg/dl)
- S. indirect bilirubin (mg/dl)
- SGOT(u/l)
- SGPT (u/l)
- S.alkaline phosphataseu/l)
- S.total protein(g/dl)
- S. albumin (g/dl)
- S.globulin (g/dl)
- S. calcium (mg/dl)
- S. phosphorous (mg/dl)

URINE EXAMINATION

- Albumin
- Sugar (Fasting & post prandial)
- Deposits
- Bile salts
- Bile pigments
- Urobilinogen

MOTION - Ova Cyst SPUTUM - AFB

D.SPECIFIC INVESTIGATION

ASO TITRE, RA FACTOR, CRP TITRE

OTHER INVESTIGATIONS

X RAY FOR KNEE JOINTS(BOTH AP/ LAT VIEW)

STUDY ENROLLMENT:

- In this clinical trial patients reporting at NIS OPD with the clinical symptoms of pain& swelling of knee joints, morning stiffness& restricted movements will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.
- The patients in this study will be be informed(Form-IVC) about theobjective of the study, trial drug, possible outcomes will in their own language and terms understandable to them.
- After ascertaining the patient's willingness, informed consent would be obtained in writing from them in the consent form .(Form- IVA)
- All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phone number etc. so as to report easily and any adverse reactions arise.
- Complete clinical history, complaints and duration, examination findings-- all will be recorded in the prescribed Proforma in the history and clinical assessment forms separately. Screening Form- I will be filled up; Form I-A, Form –II and Form –III will be used for recording the patients' history, clinical examination of symptoms and signs and laboratory investigations respectively.
- Patients would be advised to take the trial drug and appropriate dietary advice (Form IV-D) would be given according to the patients' perfect understanding.

CONDUCT OF THE STUDY:

Before starting the course purgation will be with the OP medicine Agasthiar Kuzhambu 130 mg od with ginger juice early morning in empty stomach.

The trial drug **SARVA NOI LINGA CHENDURAM** (**Internal)** is given for 7 days followed by a break (redieting) of 5 days. Again the medicine is will be for 7 days followed by a break of 5 days. Likewise the medicine is given till the end of the course .

Every first day of break(redieting) starts with head bath with the paste of Ajowan seeds and cow's milk and diet free of salt, tamarind ,etc .. noted in the form IV D (Dietary advice form). Dietary advice is strictly followed during the period of drug administration as well as redieting period.During redieting period roasted salt intake is recommended.

The trial drug **MAASHA THYLUM[ulunthu thaylum] (External)** will be given continuously for 48 days for external application

For OP patients ,they should visit the hospital once in 12 days. At each clinical visit clinical assessment is done and prognosis is noted.

For IP patients clinical assessment is done daily and prognosis is noted.

Laboratory investigations & radiological investigation are done 0 day and 24th & 48 th day of the trial for both OP & IP patients.

For IP patients, who is not in a situation to stay in the hospital for a long time is advised to attend the OPD for the continuation of the treatment. After the end of the treatment also, the patient is advised to visit the OPD for another 2months for follow-up. If any trial patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he/ she will be allowed, but defaulters of one week and more will not be allowed to continue and be withdrawn from the study with fresh case being included.

DATA MANAGEMENT

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms will be filed separately.

- The Data recordings will be monitored for completion by HOD and adverse event by Sr.Research Officer (Statistics). All forms will be further scrutinized in presence of Investigators by Sr.Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

STATISTICAL ANALYSIS:

All collected data will be entered into the computer and manually cross-checked the correctness of the data entry. The clinical symptoms and pain scale will be analysed by comparing the two point of data(before and after treatment) paired test and chi-square test will be employed to study the efficacy of treatment. Futher, the effect of age and sex will also be analysed.

OUT COME:

1.PRIMARY OUTCOME

Outcome is pain mainly assessed by **Universal Pain assessment scale-Numeric Rating Scale (13)** before and after treatment

Numeric Rating Scale (0-10) for pain :

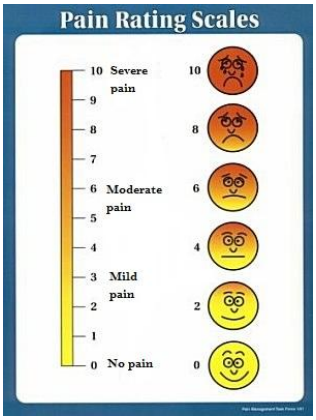
0 No pain

1-3 Mild pain (Nagging, Annoying, Interfering little with ADLs)

4-6 Moderate pain (Interferes significantly with ADLs)

7-10 Severe pain (Disabling, unable to perform ADLs)

(ADLs-Activities of daily living)



National institute of health, Warren Grant Magnuson Clinical care, pain intensity instrument – july 2003

2.SECONDARY OUTCOME

Secondary outcome is assessed by following parameters before and after treatment.

1. Reduction in other clinical symptoms
2. Restricted movement assessment scale.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction, he/she would be immediaetly withdrawn from the trial and proper management will be given in OPD of National institute of siddha.

ETHICAL ISSUES

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.

2. No other external or internal medicines will be used. There will be no infringement on the rights of patient.

3. The data collected from the patient will be kept confidentially. The patient will be informed about the diagnosis, treatment and follow-up.

4. After the consent of the patient (through consent form) they will be enrolled in the study.

5. Informed consent will be obtained from the patient explaining in the understandable language to the patient.

6. Treatment would be provided free of cost.

7. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care throughout the end.

8 .The patients who are excluded (as per exclusion criteria) are given proper treatment at National Institute of Siddha.

ASSESSMENT FORM

FORM I SCREENING AND SELECTION PROFORMA

FORM I A HISTORY PROFORMA ON ENROLLMENT

FORM ll CLINICAL ASSESSMENT ON ENROLLMENT

FORM ll A CLINICAL ASSESSMENT DURING AND AFTER TRIAL

FORM lll LABORATORY INVESTIGATION ON ENROLLMENT AND CONCLUSION OF TRIAL

FORM IV A DRUG COMPLIANCE FORM

FORM IV B INFORMATION SHEET

FORM IV C CONSENT FORM

FORM IV D DIETARY ADVICE FORM

FORM IV E WITHDRAWAL FORM

FORM IV F ADVERSE REACTION FORM

PREPARATION OF TRIAL DRUGS

PREPARATION OF THE TRIAL DRUGS

INTERNAL DRUG: SARVA NOIA LINGA CHENDURAM

REFERENCE: Anuboga vaithiya navaneetham, part 4, page no 53&54

INGREDIENTS:

Purified lingam - 1palam(35 gms)

Purified vengaram - 4 palam (140gms

METHOD OF PURIFICATION:

- **Lingam (natural red sulphide of mercury, cinnabar)**:

  Soak it in lime juice for 2 hours.

- **Vengaram (Sodium Biborate, Borax) :**

  Fry the borax well till the water content in it dried

PREPARATION

- Purified lingam is powdered first.
- Then the purified vengaram is placed in a mud plate is subjected to mild flame until it gets melted,
- Powdered lingam is then added little by little to the melted vengaram
- Stir the above said the mixture until it solidifies
- Then the solidified mixture is allowed to cool
- Finally, powder the solidified mixture and preserve it in a glass container.

DOSAGE : 130 mgs twice a day After food

ADJUVANT: Honey

இலிங்கம்

வெங்காரம்

சர்வ நோய் இலிங்க செந்தூரம்

MAASHA THYLUM [ulunthu thylum] (External.)

Ref: Vaithiya Sinthamani (Sigicha Rathina deepam) Pg no:202

INGREDIENTS:

- Ulunthu -1400 gm **- I**
- Sitramutti 1400 gm **–II**

} For decoction

- Ulunthu - 105 gm **-III**
- Aamanakku vaer - 105 gm **-IV**
- Athividayam - 105 gm **-V**
- Sitrarathai - 105 gm **-VI**
- Sirukainjchori vaer - 105 gm **-VII**
- Inthuppu - 105 gm **-VIII**
- Thanneer vittan kizangu -105 gm **-IX**

METHOD OF PREPERATION:

- ✓ Prepare decocotion from ingredient **I & II** (use 21.4 ltr water boiled the mixture is until it reduce half of the total ltrs)
- ✓ Half of the quantity of decoction is used paste for prepration with ingredients **III to IX**
- ✓ The remaining half of the quantity of decocotion is mixed with gingeely oil (gingely oil - 5.36 ltr) and subjected to boil in mild flame
- ✓ Add the paste to the boling oil, stir it well until it reaches the paste conisitency i.e mezugu patham
- ✓ Then preserve it in the glass container.

ACONITUM HETEROPHYLLUM

VIGNA MUNGO

ALPINIA GALANGA

ASPARAGUS RECEMOSUS

SIDA CARDIFOLIA

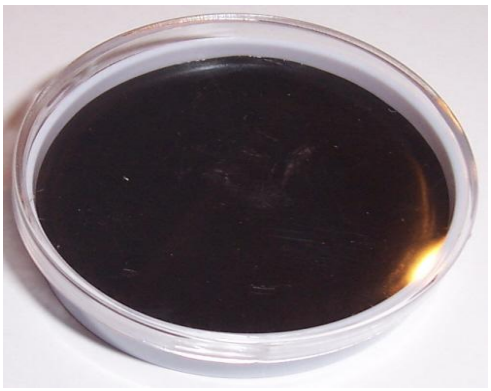
RICNUS COMMUNIS

TRAGIA INVOLUCURTA

SODIUM CHLORIDE IMPURA

SESAME OIL

மாஷ தைலம்[உளுந்து தைலம்]



Observation and Results

OBSERVATION AND RESULTS

1.Gender distribution

2.Age Distribution

3. Gunam distribution

4. Kaalam distribution

5. Dietary habits

6. Seasonal variation

7. Thinai

8. Socio-economic Status

9. Occupational status

10. Precipitating factors

11. Chronicity of illness

12. Clinical features

13. Disturbances in kanmenthiriyam

14.Disturbances in vatham

15. Disturbances in pitham

16. Disturbances in kabam

17. Udal Kattugal

18. Ennvagai Thervugal

19.Kosangal

20. Naadi

21. Neikkuri

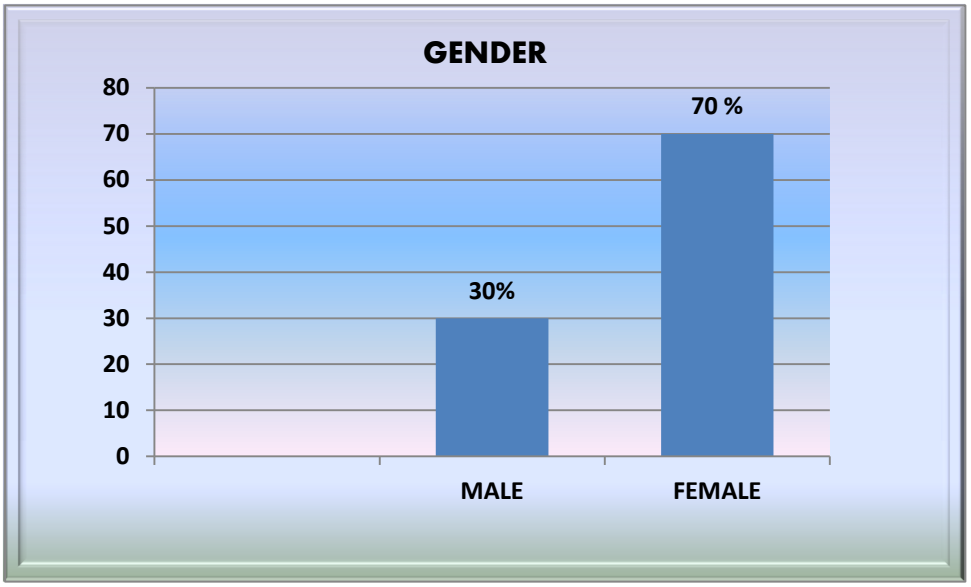
22. Involvement of knee joints

23. Outcome measurements

24. Results after treatment

1.GENDER DISTRIBUTION

GENDER	NO OF CASES	PERCENTAGE(%)
MALE	12	30
FEMALE	**28**	**70**
TOTAL	40	100

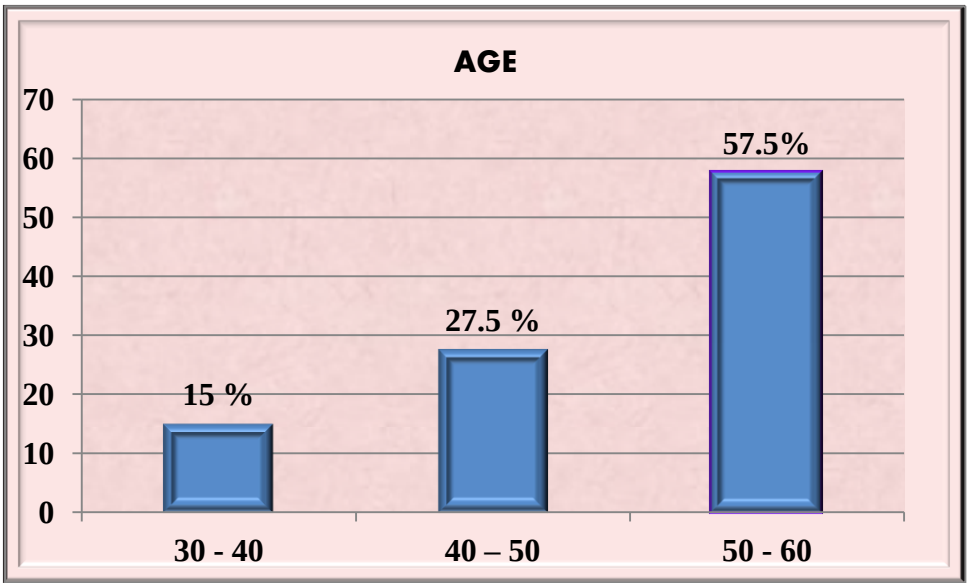


Inference:

Among the 40 cases the prevalence of the disease was found to be higher in females. i.e 70 %(28cases) and 12 cases (30%) were in male.

2.AGE DISTRIBUTION

AGE	NO OF CASES	PERCENTAGE(%)
30-40	06	15
41-50	11	27.5
51-60	**23**	**57.5**
TOTAL	40	100



Inference:

Among the 40 cases 6 cases were found in between the age group of 30 and 40. Then 11 cases (27.5%) were between 41-50, The prevalence of the disease was found to be higher in the age group 51-60 years. i.e, 23 cases(57.5%)

3.GUNAM DISTRIBUTION

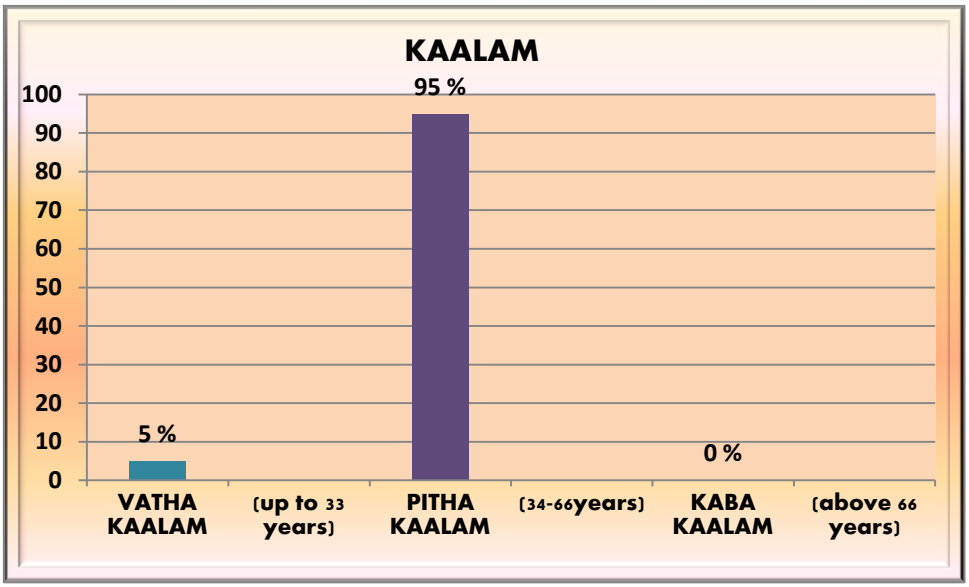
GUNAM	NO OF CASES	PERCENTAGE(%)
SATHUVA GUNAM	-	-
RASATHAM GUNAM	40	100
THAMO GUNAM	-	-
TOTAL	40	100

Inference:

All the 40 cases (100 %) were found to posses rasatha gunam

4.KAALAM DISTRIBUTION

KAALAM	NO OF CASES	PERCENTAGE(%)
VATHA KAALAM (up to 33 years)	2	5
PITHA KAALAM (34-66years)	38	95
KABA KAALAM (above 66 years)	-	-
TOTAL	40	100

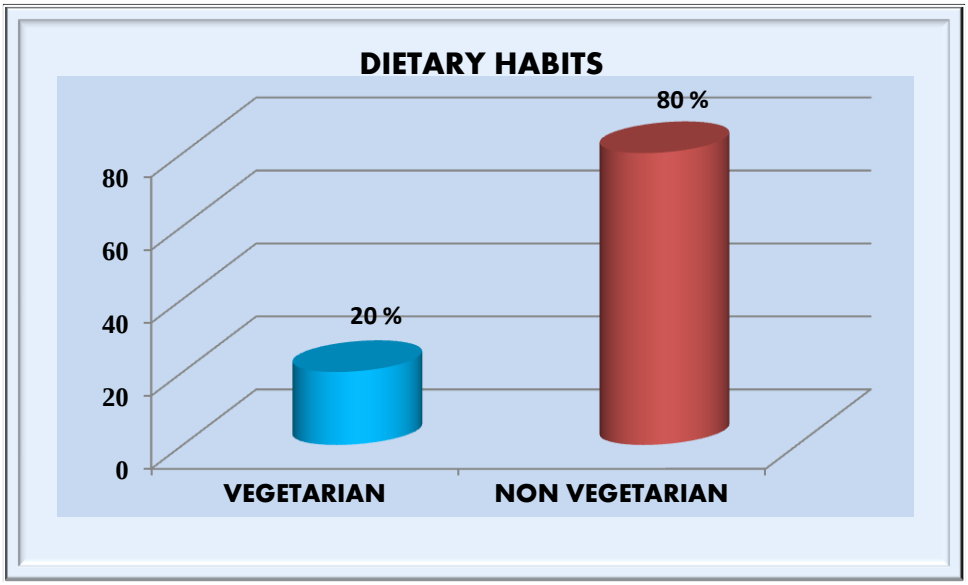


Inference:

The prevalence of the disease was found to be higher in the age group 34-66 years. i.e, pitha kaalam 38 cases(95%). Only 5% age group in 0-33 years,i.e vatha kaalam.

5.DIEATARY HABITS

DIETARY HABITS	NO OF CASES	PERCENTAGE(%)
VEGETARIAN	8	20
NON VEGETARIAN	**32**	**80**
TOTAL	40	100



Inference:

Among the 40 cases 32 cases(80%) were Non vegetarians and 8 cases(20%) were vegeterians.

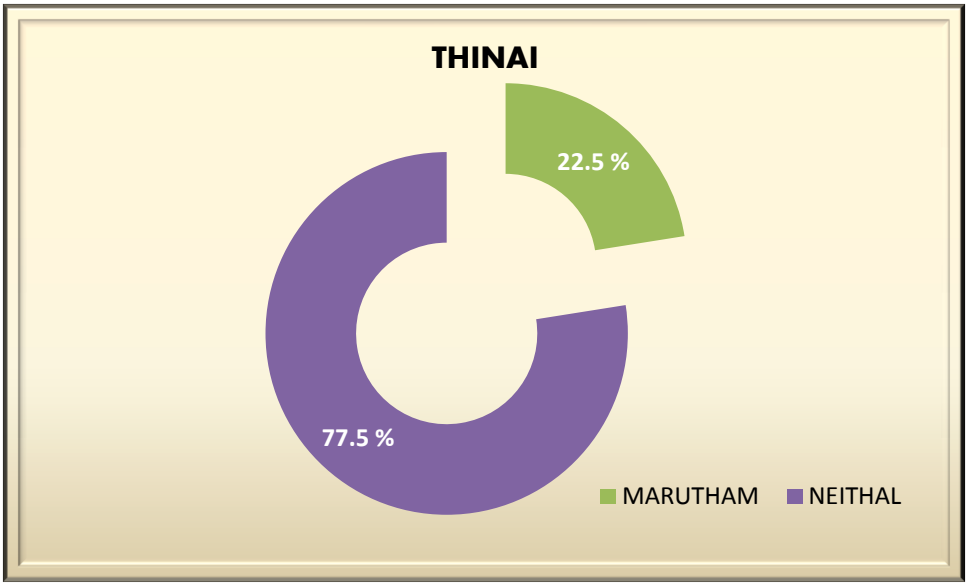
7.SEASONAL VARIATION

KAALAM	NO OF CASES	PERCENTAGE(%)
KAAR KAALAM Aug 17 – Oct 17	-	-
KOOTHIR KAALAM Oct 18 – Dec 15	-	-
MUNPANI KAALAM Dec 16 – Feb 12	-	-
PINPANI KAALAM Feb 13 – Apr 13	-	-
ELAVENIL KAALAM Apr 14 – Jun 16	-	-
MUTHUVENIL KAALAM Jun 17 – Aug 16	40	100

Inference: All the 40 cases (100 %) were admitted in muthuvenil kalam. i.e between june 17 to august 16.

8.THINAI

THINAI	NO OF CASES	PERCENTAGE(%)
KURINJI	-	-
MULLAI	-	
MARUTHAM	9	22.5
NEITHAL	31	77.5
PALAI	-	-
TOTAL	40	100

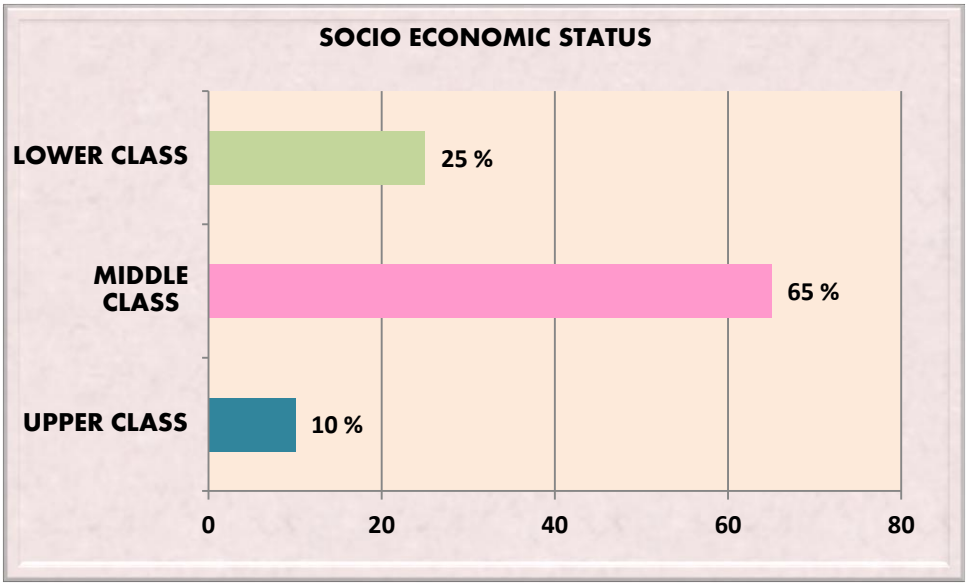


Inference:

Among the 40 cases 31 cases (77.5%) were from Neithal and 9 cases (22.5%) were from Marutham thinai.

8. SOCIO ECONOMIC STATUS

CLASS	NO OF CASES	PERCENTAGE(%)
UPPER CLASS	4	10
MIDDLE CLASS	26	65
LOWER CLASS	10	25
TOTAL	40	100

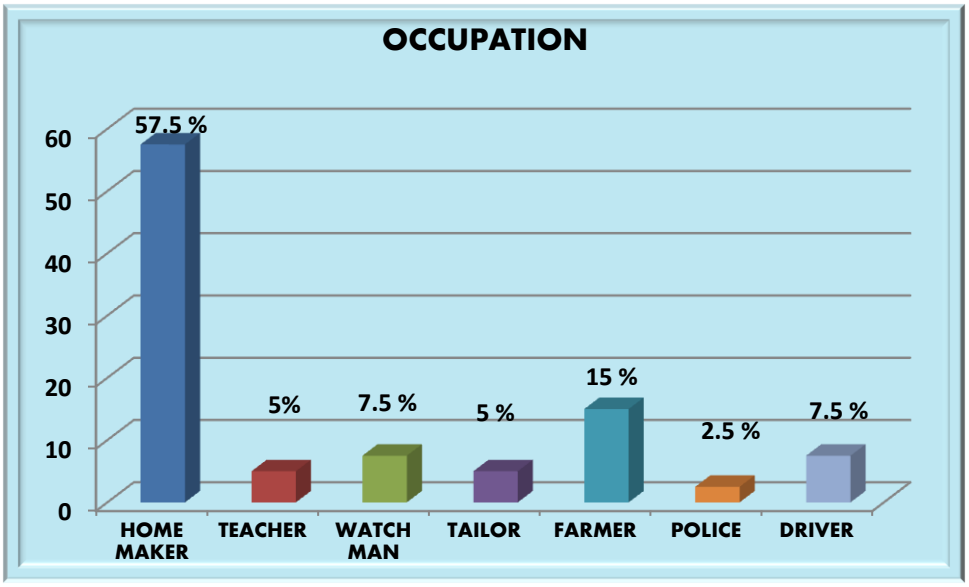


Inference:

Among the 40 cases, 26 cases (65%) were from middle class ,10 cases (25%) were from poor class, 4 cases (10%) were from rich class.

9.OCCUPATIONAL STATUS

OCCUPATION	NO OF CASES	PERCENTAGE(%)
HOME MAKER	**23**	**57.5**
TEACHER	2	5
WATCH MAN	3	7.5
TAILOR	2	5
FARMER	6	15
POLICE	1	2.5
DRIVER	3	7.5
TOTAL	40	100

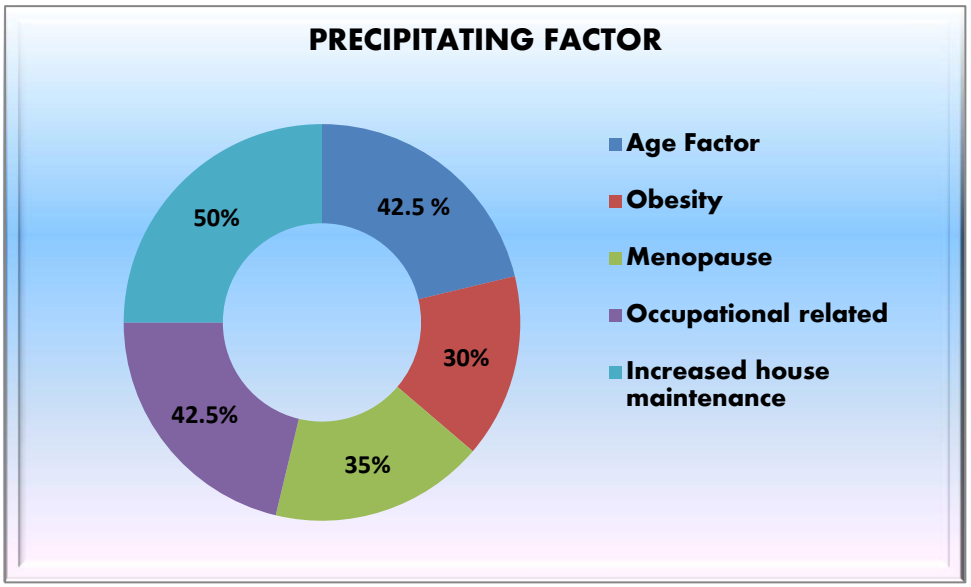


Inference:

Among the 40 patients, 23 patients (57.5 %) were homemakers, 2 patients(5%) were teacher, 3 patients (7.5 %) were watch man, 2 patients 5 %) were tailor, 6 patients (15 %) were farmer, 1 patient(2.5%) was police, 3 patients (7.5 %) were driver.

10.PRECIPITATING FACTOR

FACTORS	NO OF CASES	PERCENTAGE(%)
Age Factor	**17**	**42.5**
Obesity	12	30
Menopause	22	55
Occupational related	**17**	**42.5**
Increased house maintenance	**20**	**50**

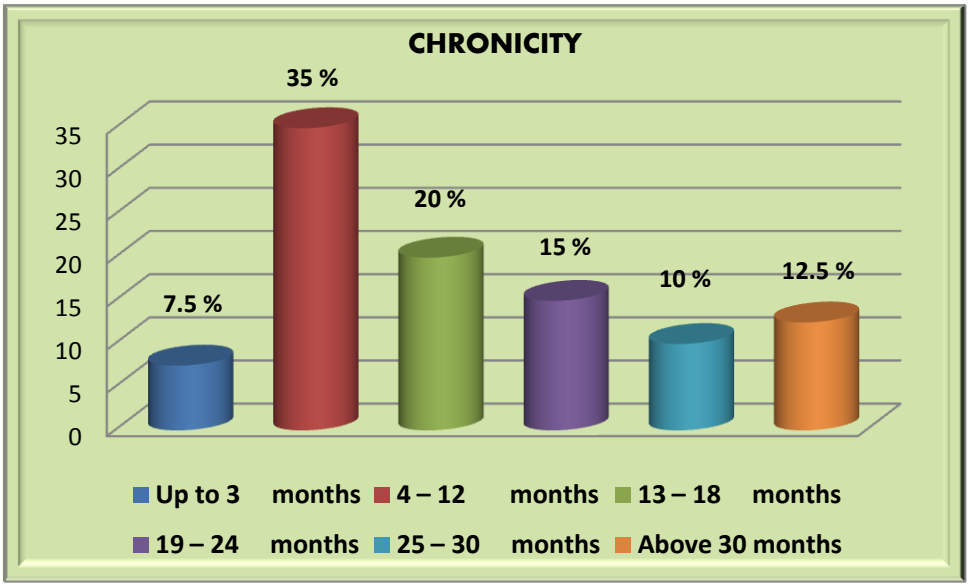


Inference :

Among the 40 patients, 14 patients (35 %) had the history of menopause, 20 cases (50 %) had the history of increased house maintenance, 12cases (30 %) had the history of obesity, 17 cases (42.5 %) had the history of occupational related, and 17 patients (42.5) had age related history.

11.CHRONICITY OF ILLNESS

CHRONICITY	NO OF CASES	PERCENTAGE(%)
Up to 3 months	3	7.5
4 – 12 months	14	35
13 – 18 months	8	20
19 – 24 months	6	15
25 – 30 months	4	10
Above 30 months	5	12.5
Total	40	100

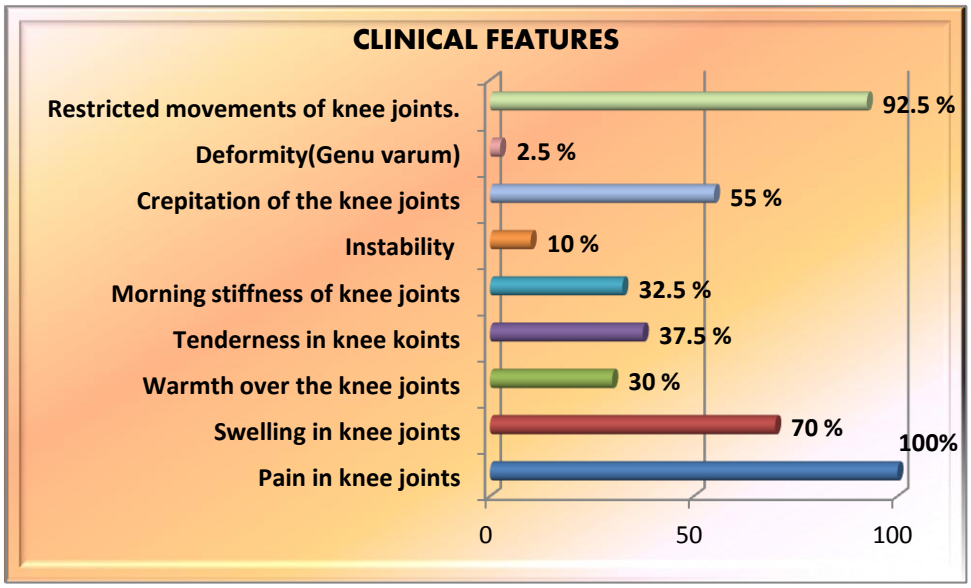


Inference :

Among the 40 cases majority of them were 4 – 12 months in their duration of illness, i.e, 14 cases(35%) and 8 patients (20%) had 13-18 months duration of illness.

12. **CLINICAL FEATURES**

CLINICAL FEAUTURES	NO OF CASES	PERCENTAGE(%)
Pain in knee joints	**40**	**100**
Swelling in knee joints	**28**	**70**
Warmth over the knee joints	12	30
Tenderness in knee koints	15	37.5
Morning stiffness of knee joints	13	32.5
Instability	04	10
Crepitation of the knee joints	22	55
Deformity(Genu varum)	01	2.5
Restricted movements of knee joints.	**37**	**92.5**



Inference :

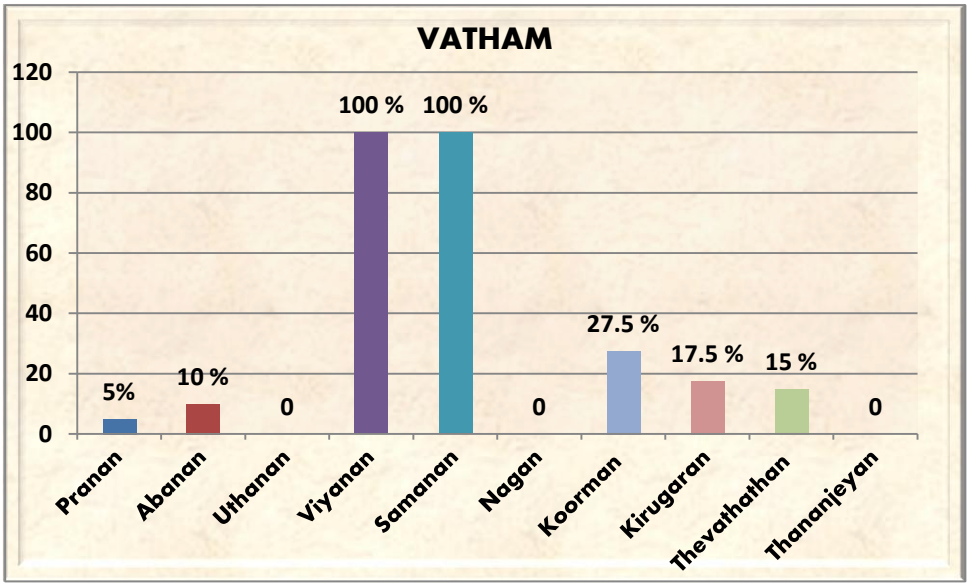
In clinical features,all the 40 cases (100%) had Pain, 13 cases (32.5%) had morning stiffness, 22 patients had crepitation(55%), restricted movements in 37 patients(92.5%) in their affected knee joints. 28 cases (70 %) had swelling, 12 cases(30%) had warmth, 15 cases (37.5 %) had tenderness, 4 cases (10%) had instability and only one patient had Genu varum deformity.

13. DISTURBANCES IN KANMENTHIRIYAM

Kaal was affected in all the 40 cases(100%) due to difficulty in walking.

14.**DISTURBANCES IN VATHAM**

VATHAM	NO OF CASES	PERCENTAGE(%)
Pranan	2	5
Abanan	4	10
Uthanan	0	0
Viyanan	40	100
Samanan	40	100
Nagan	0	0
Koorman	11	27.5
Kirugaran	7	17.5
Thevathathan	6	15
Thananjeyan	0	0

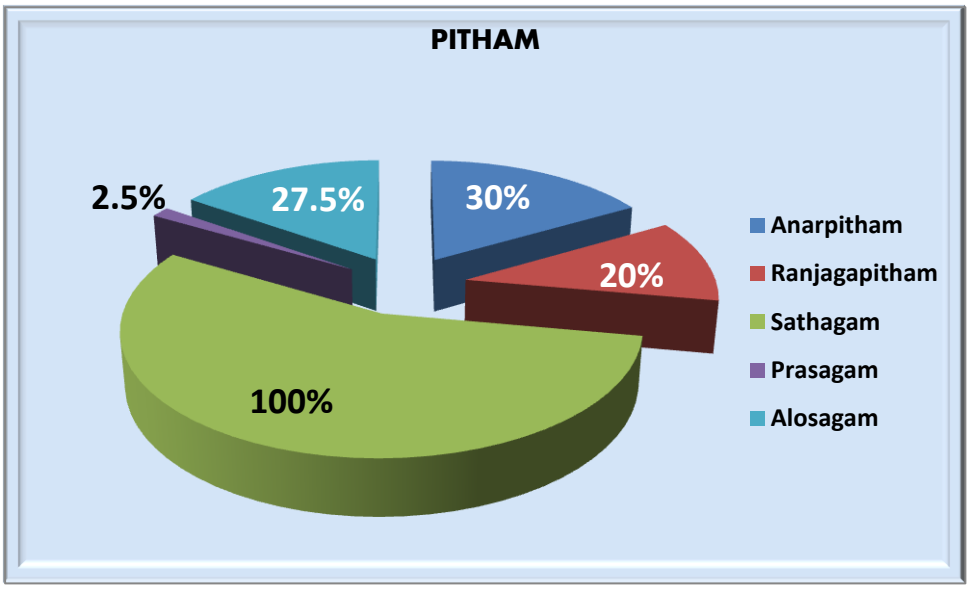


Inference :

Out of 40 cases observed ,viyanan and samanan were affected in all the 40 cases(100%) resulted in movements of knee joints , abanan was affected in 4 cases(10%) resulted constipation, koorman was affected in 11cases(27.5%) resulted in diminished vision, kirugaran was affected in7 cases,(17.5%) resulted in loss of appetite and Devathaththan was affected in 6 (15 %) cases resulted in sleeplessness.

15.DISTURBANCES IN PITHAM

PITHAM	NO OF CASES	PERCENTAGE(%)
Anarpitham	12	30
Ranjagapitham	08	20
Sathagam	40	100
Prasagam	01	2.5
Alosagam	11	27.5



Inferenecs :

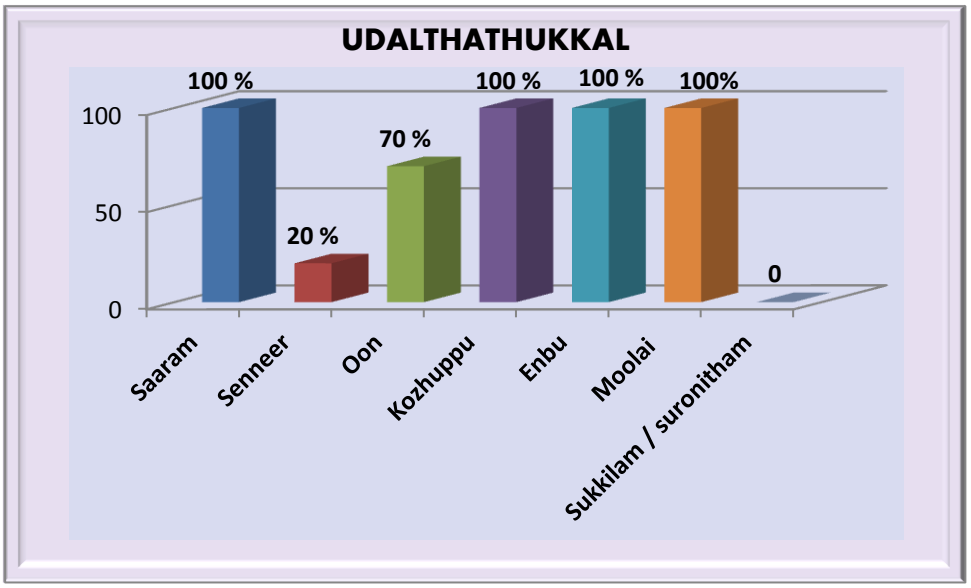
Out of 40 cases, saathaga piththam was affected in almost almost all the cases (100%) resulted in walking, anarpitham was affected in 12cases (30%) resulted in loss of appetite, alosagam was affected in 11 cases (27.5%) resulted in diminished vision, and Ranjaka piththam was affected in 8 cases (20%) resulted in pallor.

16. DISTURBANCES IN KABAM

Out of 40 cases, santhigam was affected in all the 40 cases (100%) resulted in difficulty in movements of knee joints. Avalambagam was affected due to santhigam affected.

17.UDALTHATHUKKAL

THAHTUKKAL	NO OF CASES	PERCENTAGE
Saaram	40	100
Senneer	08	20
Oon	28	70
Kozhuppu	40	100
Enbu	40	100
Moolai	40	100
Sukkilam / suronitham	0	0

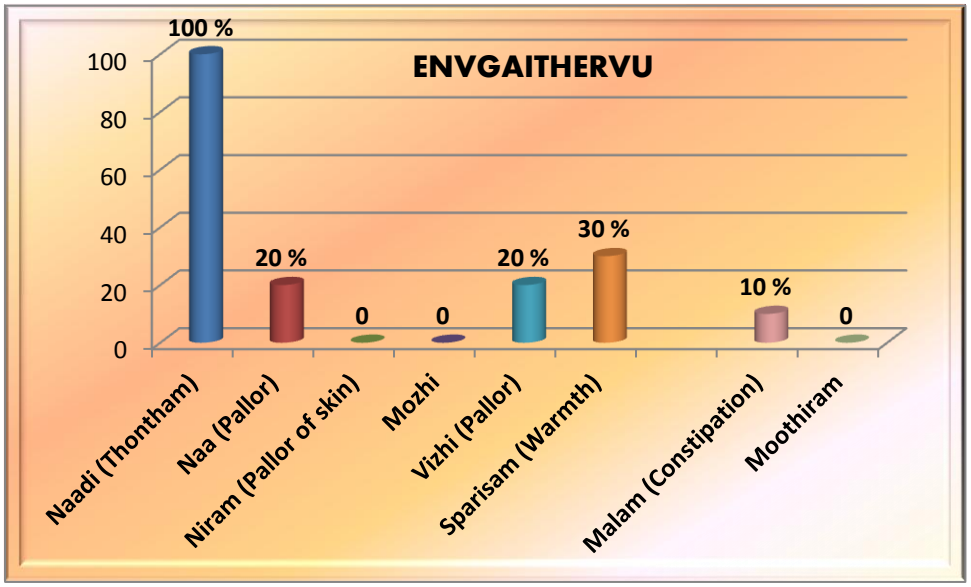


Inference:

Among the 7 udal kattugal, Saaram, Enbu, kozhuppu and moolai were affected in all the 40 cases (100 %) resulted in weakness, pain and morning stiffness occurs in affected knee joints. Oon was affected in 28 cases (70%) resulted in swelling in affected in knee joints. Senneer was affected in 8 cases (20%) resulted in pallor and reduction in haemoglobin level.

18. ENVGAI THERVUGAL

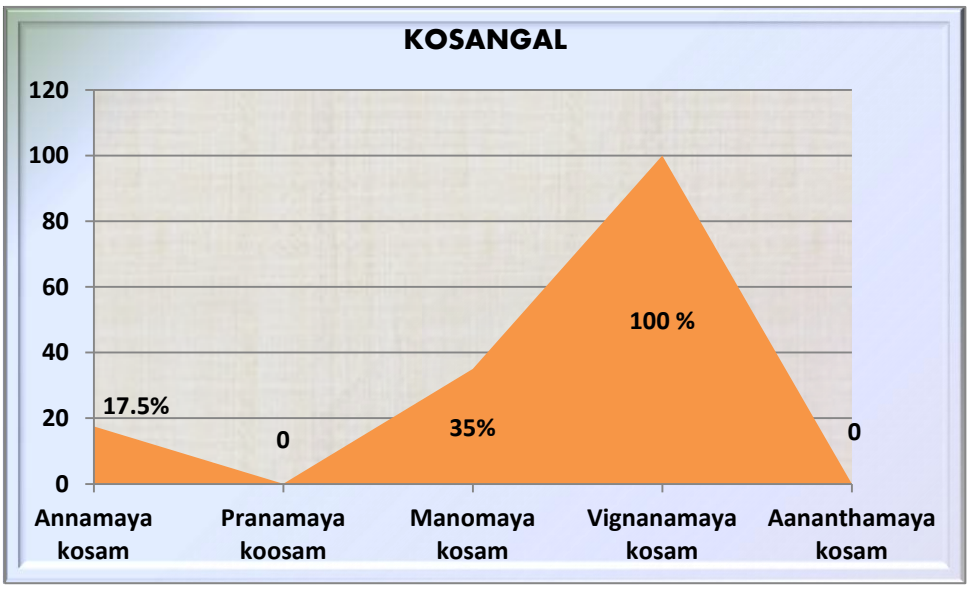
ENVAGAI THERVUGAL	NO OF CASES	PERCENTAGE
Naadi (Thontham)	40	100
Naa (Pallor)	8	20
Niram (Pallor of skin)	0	0
Mozhi	0	0
Vizhi (Pallor)	8	20
Sparisam (Warmth)	12	30
Malam (Constipation)	4	10
Moothiram	0	0



In almost all the cases altered naadi was observed most of them had vaatha pitha naadi, Malam was affected in 4cases(10%) due to constipatipn, vizhi was affected in 8 cases(20%) due to pallor and sparisam was affected in 12 cases(30%) due to warmth over the affected knee joints.

19.KOSANGAL

KOSANGAL	NO OF CASES	PERCENTAGE
Annamaya kosam	7	17.5
Pranamaya koosam	0	0
Manomaya kosam	14	35
Vignanamaya kosam	40	100
Aananthamaya kosam	0	0

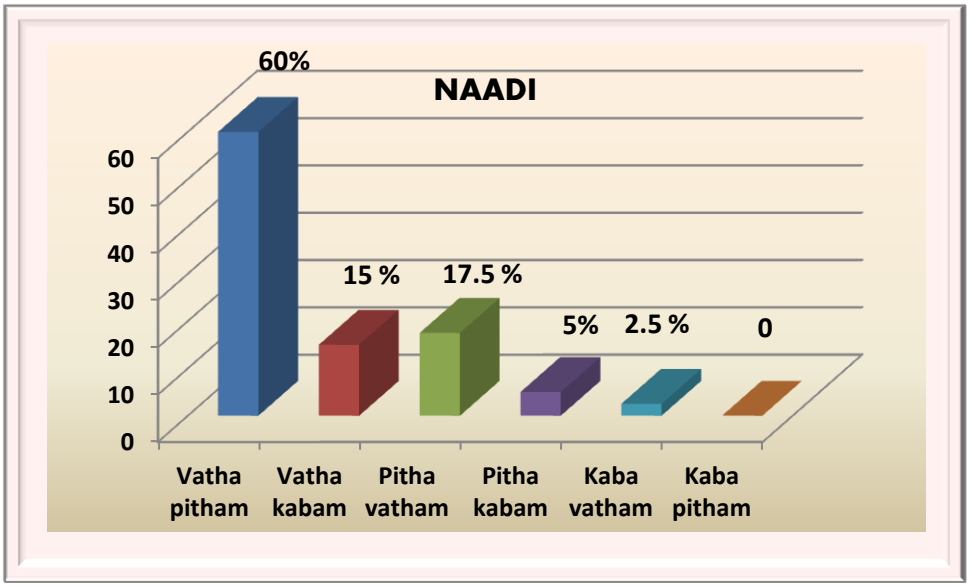


Inference:

Among the 40 cases , annamaya kosam was affected in 7 cases(25 %) resulted in loss of appetite, manomaya kosam was affected in 14 cases(35 %) resulted in depression, and vignanamaya kosam was affected in 40 cases (100 %) resulted in pain in knee joints.

20.NAADI

NAADI	NO OF CASES	PERCENTAGE
Vatha pitham	24	60
Vatha kabam	6	15
Pitha vatham	7	17.5
Pitha kabam	2	5
Kaba vatham	1	2.5
Kaba pitham	0	0
Total	40	100

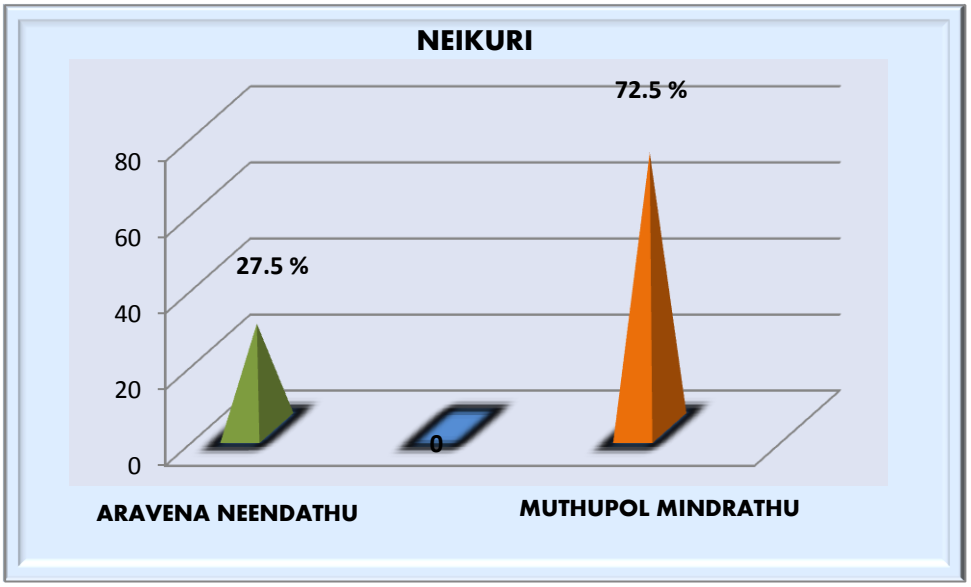


Inference :

Among the 40 cases vatha pitha nadi felt in 24 cases (60 %), pitha vatha nadi felt in 7 cases (17.5 %), pitha kaba nadi was felt in 2cases(5 %), vatha kaba nadi felt in 6 case (15 %) and kabavatham felt in only one case (2.5%)

21. NEIKURI

NEIKURI	NO OF CASES	PERCENTAGE(%)
ARAVENA NEENDATHU **(vatha neer -lengthening like a snake)**	11	27.5
AAZHI POL PARAVIATHU **(pitha neer – spreading like a ring)**	0	0
MUTHTHU POL NINRATHU **(kaba neer – appears like a pearl)**	29	72.5
TOTAL	40	100



Inference:

Among the 40 cases,in 29cases (72.5 %) the neikuri was observed as kaba neer and 11 cases (27.5 %) observed as vaatha neer.

X-RAY OF KNEE OSTEOARTHRITIS

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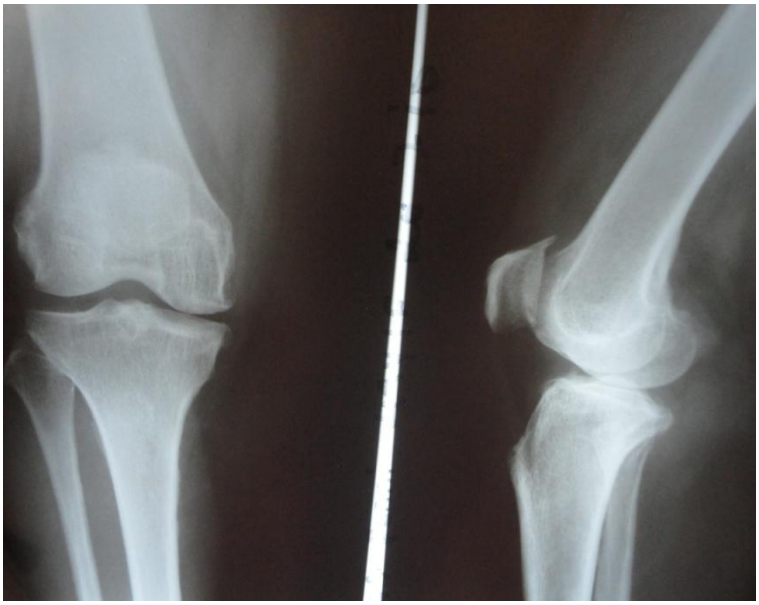
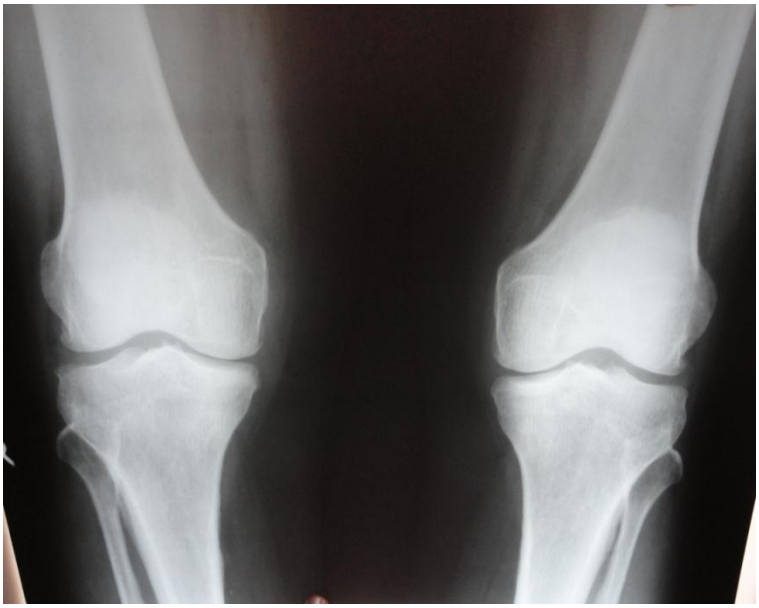
A/S : 60 / M

IP NO :3985
A/S : 54 / F



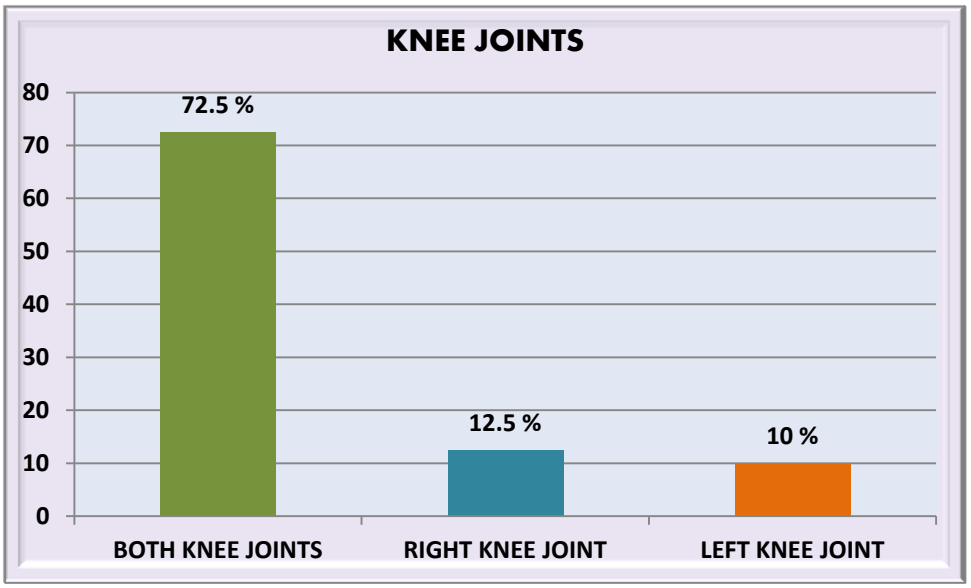
OP NO : C53913
A/S : 52/ F



OP NO : C72639
A/S : 45/ M

22. **INVOLVEMENT OF KNEE JOINTS**

KNEE JOINTS	NO OF CASES	PERCENTAGE(%)
Both knee joints	**31**	**77.5**
Right knee joint only	5	12.5
Left knee joint only	4	10
Total	40	100



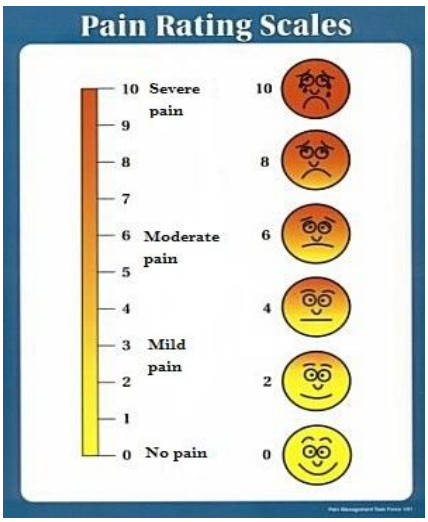
Inference :

Among the 40 patients, in 31 cases(77.5%) the disease was affected in both knee joints, in 5 cases(12.5%) it was only in right knee joint only,4 cases(10%) found in left knee joint only.

23.OUTCOME MEASUREMENTS

- PRIMARY OUTCOME

PAIN SCALE	BEFORE TREATMENT		AFTER TREATMENT	
	NO OF CASES	PERCENTGAE(%)	NO OF CASES	PERCENTGAE(%)
NO PAIN [0]	0	0	23	57.5
MILD PAIN [1-3]	14	35	11	27.5
MODERATE PAIN [4-6]	19	47.5	6	15
SEVERE[7-10]	7	17.5	0	0



Numeric Rating Scale (0-10) for pain

0	No pain
1-3	Mild pain (Nagging, Annoying, Interfering little with ADLs)
4-6	Moderate pain (Interferes significantly with ADLs)
7-10	Severe pain (Disabling, unable to perform ADLs)

(ADLs-Activities of daily living)

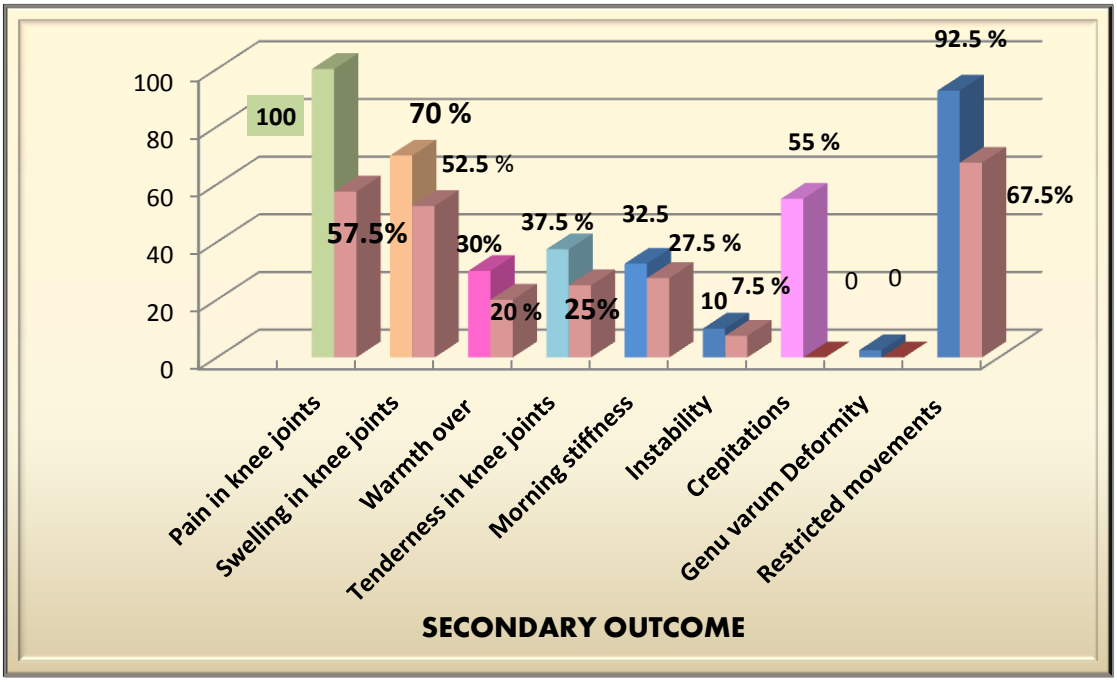
Reference –National institute of health, Warren Grant magnuson clinical care, pain intensity instruments-july 2003

Inference:

Among the 40 cases, after treatment there was no pain in 23 cases (57.5%), mild pain in 11 cases (27.5%), and moderate pain in 6 cases(15%).

- SECONDARY OUTCOME

CLINICAL FEATURES	BT	AT	BT (%)	SYMPTOMS REDUCED	AT %
Pain in knee joints	40	17	**100**	23	**57.5**
Swelling in knee joints	28	7	**70**	21	**52.5**
Warmth over	12	4	30	8	20
Tenderness in knee joints	15	5	37.5	10	25
Morning stiffness	13	2	32.5	11	27.5
Instability	04	1	10	3	7.5
Crepitations	22	22	55	0	0
Genu varum Deformity	01	1	2.5	0	0
Restricted movements	37	10	**92.5**	27	**67.5**

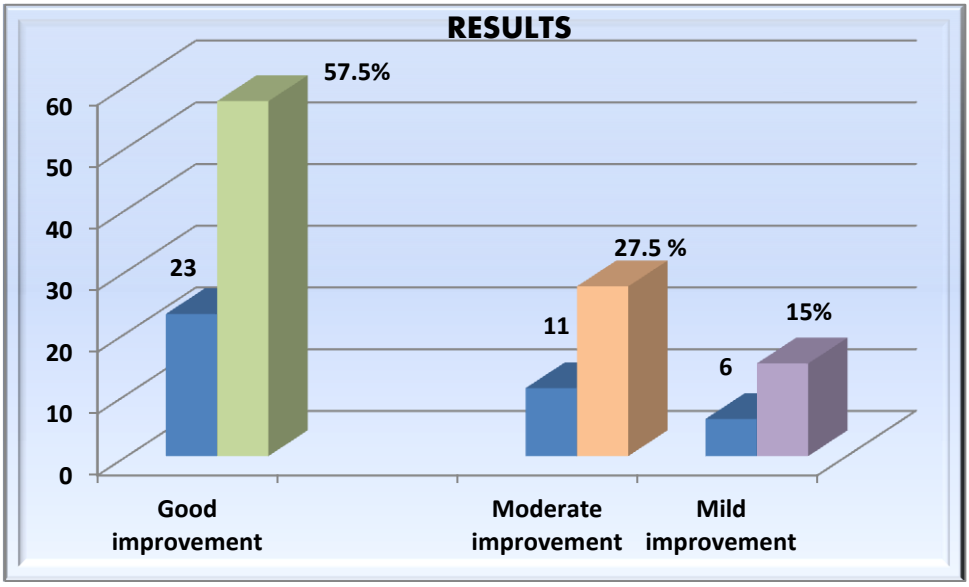


Inference:

After treatment 23 cases had relieved from pain, 21 cases had relieved from swelling, 8 cases had relieved from warmth, 10 cases had relieved from tenderness, 11 cases had relieved from morning stiffness, 3 cases had relieved from instability, 27 cases had relieved from restricted movements.

24.RESULTS

RESULTS	NO OF CASES	PERCENTAGE(%)
Good improvement	23	57.5
Moderate improvement	11	27.5
Mild improvement	6	15
Total	40	100



Inference:

Out of the 40 cases good improvement was observed in 23 patients (57.5 %), moderate improvement in 11 patients (27.5 %) and mild improvement in 6 patients (15)

RESULT	FROM	TO
GOOD	1-3 and 4-6	0
MODERATE	4-6	1-3
MILD	7-10	4-6

PAIN ASSESSMENT SCALE

SL. NO	OP/IP NO	NAME	Age/sex	PAIN ASSESSMENT SCALE	
				Before treatment	After treatment
1.	C 80468	Mrs. V.Vijayakumari	55/F	2	0
2.	C 80519	Mrs. C.Kanniyammal	38/F	4	0
3.	C 78091	Mrs. R.Pushpalatha	42/F	3	0
4.	C 73170	Mr. C.Ravikumar	58/M	5	1
5.	C 42985	Mr. G.Sivakumar	43/M	2	0
6.	C 40346	Mrs. V.Kavitha	32/F	1	0
7.	C 53913	Mrs. B.Poongothai	52/F	6	2
8.	C 31928	Mrs. P.Selvi	40/F	4	0
9.	C 66825	Mrs. M.Sudha	45/F	5	0
10.	C 14089	Mrs. M.Krishnaveni	45/F	3	0
11.	C 82185	Mrs. J.Roselin	48/F	6	2
12.	C 61182	Mrs. R.Anjalidevi	39/F	5	1
13.	C 81090	Mrs. A.Visalatchi	36/F	2	0
14.	C 40799	Mrs. I.Girija	44/F	2	0
15.	C 23304	Mrs. G.Manimegalai	53/F	5	1
16.	C 78695	Mrs. D.Mala	54/F	3	0
17.	C 80538	Mrs. S.Tamilmani	58/F	9	6
18.	C 10440	Mrs. K.Bhuvaneswari	40/F	4	0
19.	C 52539	Mrs. K.Banumathi	55/F	7	2
20.	C 73713	Mr. R.Paramasivam	60/M	2	0
21.	C 83683	Mr.B.Shanmugasundaram	48/M	3	0
22.	C 3464	Mrs. C.Rani	60/F	1	0
23.	C 61756	Mrs. B.Suseela	60/F	8	5
24.	C 73565	Mrs. R.Aadhilakshmi	60/F	5	1
25.	B 20623	Mrs. Saraswathi	52/F	4	0
26.	C 81675	Mrs. P.Santhnam	39/F	6	2
27.	C 83165	Mr. S.Muniyan	45/M	5	3
28.	C 85803	Mr. R. Srinivasan	60/M	3	0
29.	C 72639	Mr. P.Senthikumar	45/M	3	0
30.	C 85465	Mr. S.Srinivasan	42/M	6	2
31.	4878	Mr. M.Kuppusamy	58/M	5	0
32.	4958	Mr. M.Velusami	60/M	5	2
33.	4911	Mr. M.Wahab	55/M	9	6
34.	4953	Mr. C.Santhanam	58/M	4	0
35.	3958	Mrs. C.Anthoniammal	50/F	9	4
36.	3985	Mrs. S.Suseela	54/F	8	5
37.	4019	Mrs. S.Mahalakshmi	47/F	5	0
38.	4017	Mrs. G.Baby	32/F	3	0
39.	4046	Mrs.Lakshmi	52/F	4	0
40.	4078	Mrs. D.Kaliyammal	55/F	9	6

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

Mean and Standard deviation of pain score at start, during and end of treatment

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	painb	4.63	40	2.238	.354
	paina	1.27	40	1.935	.306

Paired Samples Test

		t	df	Sig. (2-tailed)
Pair 1	painb - paina	20.154	39	0.001

The mean± standard deviation of pain score at before and after treatment were 4.63 ± 2.24 and 1.27 ± 1.93 respectively which is statistically significant (t= 20.154 p<0.001).

Hb and RBC – INVESTIGATIONS BEFORE AND AFTER TREATMENT – IN IP & OP PATIENTS

SL NO	OP/IP NO	NAME	Age/sex	Hb gm%		TRBC Million cells /cumm	
				Before treatment	After treatment	Before treatment	After treatment
1.	C 80468	Mrs. V.Vijayakumari	55/F	10.9	11	3.8	5.0
2.	C 80519	Mrs. C.Kanniyammal	38/F	12.7	12.5	4.2	4.3
3.	C 78091	Mrs. R.Pushpalatha	42/F	10.1	12.0	4.4	4.7
4.	C 73170	Mr. C.Ravikumar	58/M	14.8	15.0	5.0	5.1
5.	C 42985	Mr. G.Sivakumar	43/M	15.2	14.8	4.3	4.9
6.	C 40346	Mrs. V.Kavitha	32/F	13.6	14.0	4.9	4.7
7.	C 53913	Mrs. B.Poongothai	52/F	12.8	13.8	4.5	4.6
8.	C 31928	Mrs. P.Selvi	40/F	9.8	15.9	3.9	4.0
9.	C 66825	Mrs. M.Sudha	45/F	13.5	13.5	4.6	5.1
10.	C 14089	Mrs. M.Krishnaveni	45/F	12.1	12.5	5.0	4.9
11.	C 82185	Mrs. J.Roselin	48/F	12.2	13.3	5.1	5.3
12.	C 61182	Mrs. R.Anjalidevi	39/F	10.0	12.5	4.2	4.8
13.	C 81090	Mrs. A.Visalatchi	36/F	12.8	14.9	4.9	4.7
14.	C 40799	Mrs. I.Girija	44/F	9.3	10.0	4.2	4.3
15.	C 23304	Mrs. G.Manimegalai	53/F	8.9	10.5	4.5	4.2
16.	C 78695	Mrs. D.Mala	54/F	11.9	11.0	4.7	4.8
17.	C 80538	Mrs. S.Tamilmani	58/F	10.0	12.6	4.1	4.1
18.	C 10440	Mrs. K.Bhuvaneswari	40/F	14.8	13.5	4.9	4.6
19.	C 52539	Mrs. K.Banumathi	55/F	12.8	16.3	4.1	4.2
20.	C 73713	Mr. R.Paramasivam	60/M	15.5	16.0	5.6	5.1
21.	C 83683	Mr.B.Shanmugasundaram	48/M	15.3	15.8	5.4	5.4
22.	C 3464	Mrs. C.Rani	60/F	12.9	13.0	4.9	5.1
23.	C 61756	Mrs. B.Suseela	60/F	12.7	14.3	5.1	4.9
24.	C 73565	Mrs. R.Aadhilakshmi	60/F	13.3	14.3	5.0	4.9
25.	B 20623	Mrs. Saraswathi	52/F	13.6	15.3	4.5	4.2
26.	C 81675	Mrs. P.Santha	39/F	13.7	14.0	4.6	4.8
27.	C 83165	Mr. S.Muniyan	45/M	16.5	16.1	5.5	4.3
28.	C 85803	Mr. R. Srinivasan	60/M	14.2	15.5	4.6	4.3
29.	C 72639	Mr. P.Senthikumar	45/M	14.5	13.9	4.9	4.8
30.	C 85465	Mr. S.Srinivasan	42/M	15.1	15.2	5.1	5.0
31.	4878	Mr. M.Kuppusamy	58/M	13.2	13.2	4.6	5.2
32.	4958	Mr. M.Velusami	60/M	9.5	10.0	3.7	4.0
33.	4911	Mr. M.Wahab	55/M	15.7	15.2	5.2	4.9
34.	4953	Mr. C.Santhanam	58/M	12.6	13.0	4.2	3.9
35.	3958	Mrs. C.Anthoniammal	50/F	16.3	16.1	5.0	4.3
36.	3985	Mrs. S.Suseela	54/F	14.2	1230	4.6	5.1
37.	4019	Mrs. S.Mahalakshmi	47/F	13.6	12.7	4.4	4.1
38.	4017	Mrs. G.Baby	32/F	12.0	13.6	4.4	4.6
39.	4046	Mrs.Lakshmi	52/F	9.4	11.5	4.1	5.1
40.	4078	Mrs. D.Kaliyammal	55/F	11.4	11.9	3.9	4.1

CHOLESTEROL PROFILE OF THE OPD AND IPD PATIENTS (BEFORE AND AFTER TREATMENT)

S. NO	OP/IP NO	Age/sex	T.CHOLESTEROL mg/dl		HDL mg/dl		LDL mg/dl		VLDL mg/dl		TGL mg/dl	
			BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	C 80468	55/F	231	238	36	38	157	160	38	39	192	196
2.	C 80519	38/F	218	186	64	41	131	119	23	26	117	125
3.	C 78091	42/F	214	193	53	36	123	127	28	30	131	152
4.	C 73170	58/M	230	220	35	36	163	127	55	16	169	159
5.	C 42985	43/M	265	259	49	36	186	186	30	37	153	182
6.	C 40346	32/F	125	193	51	49	127	127	17	17	90	84
7.	C 53913	52/F	245	247	38	39	184	184	23	23	113	117
8.	C 31928	40/F	170	165	40	38	110	107	20	20	161	159
9.	C 66825	45/F	180	178	45	46	115	115	30	29	92	95
10.	C 14089	45/F	116	190	36	38	146	131	14	21	72	105
11.	C 82185	48/F	200	164	42	35	112	125	36	18	189	100
12.	C 61182	39/F	195	190	30	26	142	132	25	25	160	141
13.	C 81090	36/F	154	160	36	40	100	100	19	20	91	93
14.	C 40799	44/F	152	149	36	40	100	102	35	26	111	121
15.	C 23304	53/F	202	205	36	35	156	150	16	20	84	90
16.	C 78695	54/F	171	180	36	45	106	110	29	25	148	150
17.	C 80538	58/F	204	205	30	36	135	137	39	27	158	150
18.	C 10440	40/F	180	175	30	33	132	129	18	16	157	155
19.	C 52539	55/F	235	210	67	45	114	120	54	45	200	180
20.	C 73713	60/M	199	168	40	37	139	112	20	19	100	97
21.	C 83683	48/M	141	118	36	35	18	70	25	13	110	66
22.	C 3464	60/F	241	200	48	50	153	105	40	45	203	180
23.	C 61756	60/F	260	245	38	62	190	157	32	26	162	133
24.	C 73565	60/F	195	190	31	33	142	129	22	20	110	115
25.	B 20623	52/F	169	172	49	50	98	98	22	24	155	155
26.	C 81675	39/F	205	205	42	44	128	121	20	35	165	160
27.	C 83165	45/M	198	200	40	40	122	124	36	36	169	170
28.	C 85803	60/M	210	207	36	44	138	138	26	25	169	135
29.	C 72639	45/M	210	208	48	38	136	159	36	11	116	120
30.	C 85465	42/M	231	238	36	38	157	160	38	39	192	196
31.	4878	58/M	218	186	64	41	131	119	23	26	117	125
32.	3958	50/F	214	193	53	36	123	127	28	30	131	152
33.	4911	55/M	231	200	32	30	153	125	50	45	168	160
34.	4953	58/M	180	175	30	33	132	129	18	16	157	155
35.	4958	60/M	235	210	67	45	114	120	54	45	200	180
36.	3985	54/F	220	225	55	47	112	126	49	44	201	179
37.	4019	47/F	126	143	26	33	66	65	16	16	80	80
38.	4017	32/F	145	146	26	33	58	62	17	18	189	182
39.	4046	52/F	200	198	27	34	56	60	18	24	201	179
40.	4078	55/F	158	170	35	30	120	079	26	22	153	109

LAB INVESTIGATIONS BEFORE TREATMENT

Sno	OP/IP No	Age/Sex	TC Cells/ cumm	DC%				ESR		Blood sugar mg/dl		Blood urea mg/dl	S. Creat.	S.Uric acid mg/dl	ASO	CRP	RA Factor
				P	L	E	M	1/2 hr	1 hr	F	PP						
1	C80468	55/F	8800	74	23	3	0	10	30	102	120	35	1.0	6.1	- ve	- ve	- ve
2	C80519	38/F	6600	55	40	4	1	4	20	100	120	26	0.8	3.7	- ve	- ve	- ve
3	C78091	42/F	6500	49	47	4	0	4	10	74	126	22	0.7	4.6	- ve	- ve	- ve
4	C73170	58/M	8400	54	41	4	1	2	4	121	135	16	0.5	6.5	- ve	- ve	- ve
5	C42985	43/M	8900	69	23	7	1	10	20	102	139	21	0.7	5.8	- ve	- ve	- ve
6	C40346	32/F	9500	60	33	6	1	6	16	117	149	18	0.5	5.7	- ve	- ve	- ve
7	C53913	52/F	9100	60	12	4	2	8	16	106	128	22	0.7	3.9	- ve	- ve	- ve
8	C31928	40/F	9400	60	33	5	2	10	22	101	131	15	0.5	6.9	- ve	- ve	- ve
9	C66825	45/F	8400	65	33	2	0	6	14	84	94	23	0.6	6.0	- ve	- ve	- ve
10	C14089	45/F	9100	70	24	5	1	2	8	78	108	35	0.9	7.0	- ve	- ve	- ve
11	C82185	48/F	6300	70	25	5	0	10	22	92	138	25	0.8	4.6	- ve	- ve	- ve
12	C61182	39/F	10400	60	33	7	0	18	38	85	123	26	0.8	4.3	- ve	- ve	- ve
13	C81090	36/F	7400	61	36	3	0	2	4	80	105	25	0.5	3.1	- ve	- ve	- ve
14	C40799	44/F	6000	60	36	3	1	4	8	106	126	16	0.7	5.7	- ve	- ve	- ve
15	C23304	53/F	6900	65	33	2	0	2	4	97	123	26	0.8	7.0	- ve	- ve	- ve
16	C78695	54/F	6000	56	39	5	0	2	12	89	131	22	0.7	4.5	- ve	- ve	- ve
17	C80538	58/F	6300	60	33	5	2	4	12	99	143	36	0.9	4.7	- ve	- ve	- ve
18	C10440	40/F	7700	60	35	5	0	8	22	105	143	16	0.5	3.3	- ve	- ve	- ve
19	C52539	55/F	7200	49	43	8	0	4	14	97	117	24	0.7	3.4	- ve	- ve	- ve
20	C73713	60/M	6600	59	37	4	3	2	4	90	120	22	0.7	5.6	- ve	- ve	- ve
21	C83683	48/M	9300	71	24	4	1	6	14	100	124	21	0.6	6.9	- ve	- ve	- ve
22	C 3464	60/F	6200	55	40	5	0	6	14	93	105	30	0.9	4.5	- ve	- ve	- ve
23	C61756	60/F	9800	13	23	4	0	20	46	87	123	19	0.6	5.9	- ve	- ve	- ve
24	C73565	60/F	7500	69	25	5	1	6	12	99	115	14	0.5	4.5	- ve	- ve	- ve
25	B20623	52/F	8200	72	23	5	0	16	36	104	141	32	1.0	4.2	- ve	- ve	- ve
26	C81675	39/F	6400	61	33	5	1	6	8	92	105	23	0.8	5.2	- ve	- ve	- ve
27	C83165	45/M	8300	60	32	8	0	4	8	80	116	15	0.4	3.6	- ve	- ve	- ve
28	C85803	60/M	6400	63	36	1	0	8	16	80	148	21	0.6	5.7	- ve	- ve	- ve
29	C72639	45/M	8900	67	28	5	0	8	16	75	85	18	0.5	7.1	- ve	- ve	- ve
30	C85465	42/M	8300	70	20	8	2	5	10	101	140	23	0.7	4.2	- ve	- ve	- ve
31	4878	58/M	8000	53	43	4	0	10	20	74	101	21	0.6	4.3	- ve	- ve	- ve
32	4958	60/M	7800	69	30	1	0	12	24	66	101	19	0.6	4.6	- ve	- ve	- ve
33	4911	55/M	10400	50	48	2	0	6	12	92	121	29	0.7	3.0	- ve	- ve	- ve
34	4953	58/M	7000	55	43	1	1	6	12	90	98	16	0.6	3.4	- ve	- ve	- ve
35	3958	50/F	7800	70	29	1	0	6	12	95	136	26	0.6	6.0	- ve	- ve	- ve
36	3985	54/F	6400	50	46	4	0	12	24	74	84	16	0.8	3.5	- ve	- ve	- ve
37	4019	47/F	8000	56	40	4	0	2	8	90	120	16	0.5	4.8	- ve	- ve	- ve
38	4017	32/F	8600	55	42	3	0	4	8	108	132	42	0.9	4.6	- ve	- ve	- ve
39	4046	52/F	11000	60	36	3	2	10	20	93	105	28	0.7	6.1	- ve	- ve	- ve
40	4078	55/F	9300	42	39	19	0	4	8	100	117	27	0.7	6.3	- ve	- ve	- ve

LAB INVESTIGATIONS AFETR TREATMENT

Sno	OP/IP No	Age/Sex	TC Cells/ cumm	DC%				ESR		Blood sugar mg/dl		Blood urea mg/dl	S. Creat.	S.Uric acid mg/dl	ASO	CRP	RA Factor
				P	L	E	M	1/2 hr	1 hr	F	PP						
1	C80468	55/F	7100	60	36	2	2	20	40	108	120	16	0.6	2.7	- ve	- ve	- ve
2	C80519	38/F	6600	66	36	1	3	10	20	130	105	18	0.5	2.9	- ve	- ve	- ve
3	C78091	42/F	8000	57	42	1	0	8	16	77	97	15	0.6	6.5	- ve	- ve	- ve
4	C73170	58/M	7900	55	44	1	0	2	4	98	109	15	0.6	4.9	- ve	- ve	- ve
5	C42985	43/M	6900	57	39	2	2	4	8	77	99	15	0.6	3.1	- ve	- ve	- ve
6	C40346	32/F	7600	66	30	2	2	8	16	104	114	22	0.6	4.3	- ve	- ve	- ve
7	C53913	52/F	11400	43	55	2	0	8	16	103	115	27	0.7	4.1	- ve	- ve	- ve
8	C31928	40/F	8000	70	26	3	1	14	28	74	86	20	0.6	4.1	- ve	- ve	- ve
9	C66825	45/F	6800	68	37	5	0	8	16	100	120	25	0.7	3.7	- ve	- ve	- ve
10	C14089	45/F	8400	50	48	2	0	10	20	96	109	25	6	4.8	- ve	- ve	- ve
11	C82185	48/F	6900	48	48	2	2	6	12	100	110	35	0.8	4.6	- ve	- ve	- ve
12	C61182	39/F	6500	50	45	3	2	6	12	97	110	25	0.8	5	- ve	- ve	- ve
13	C81090	36/F	9800	62	32	4	2	6	12	100	140	27	0.8	3.6	- ve	- ve	- ve
14	C40799	44/F	9500	50	45	3	2	6	12	108	135	30	0.8	4.5	- ve	- ve	- ve
15	C23304	53/F	8400	59	36	4	1	6	12	100	120	45	1	5	- ve	- ve	- ve
16	C78695	54/F	8000	60	38	2	0	3	6	110	120	28	0.7	3.5	- ve	- ve	- ve
17	C80538	58/F	8000	64	34	2	0	3	6	100	110	30	0.8	5	- ve	- ve	- ve
18	C10440	40/F	7000	52	45	2	1	4	8	110	140	15	0.6	6.5	- ve	- ve	- ve
19	C52539	55/F	7900	58	40	2	0	4	8	85	95	18	0.6	3.1	- ve	- ve	- ve
20	C73713	60/M	5500	15	42	5	3	6	12	106	115	15	0.6	3.8	- ve	- ve	- ve
21	C83683	48/M	7500	17	28	3	1	8	16	106	132	17	0.8	4	- ve	- ve	- ve
22	C 3464	60/F	7600	48	37	2	3	8	16	94	106	31	0.8	3.4	- ve	- ve	- ve
23	C61756	60/F	8500	62	30	8	0	6	12	66	101	17	0.6	3.2	- ve	- ve	- ve
24	C73565	60/F	7900	54	45	1	0	8	16	85	104	16	0.6	4.1	- ve	- ve	- ve
25	B20623	52/F	7200	60	45	3	2	6	12	95	110	18	0.8	3.6	- ve	- ve	- ve
26	C81675	39/F	7800	70	28	1	1	6	12	80	130	28	0.7	4.1	- ve	- ve	- ve
27	C83165	45/M	6400	58	38	2	2	8	16	90	120	20	0.6	3.5	- ve	- ve	- ve
28	C85803	60/M	9400	65	33	2	0	6	12	110	120	50	0.6	2.6	- ve	- ve	- ve
29	C72639	45/M	8200	58	37	5	0	14	28	104	135	16	0.6	4.6	- ve	- ve	- ve
30	C85465	42/M	7500	60	40	4	2	7	14	105	120	30	0.9	4.2	- ve	- ve	- ve
31	4878	58/M	7800	70	28	1	1	6	12	80	130	28	0.7	4.1	-ve	- ve	- ve
32	4958	60/M	6400	58	38	2	2	8	16	90	120	20	0.6	3.5	- ve	- ve	- ve
33	4911	55/M	9400	65	33	2	0	6	12	110	120	50	0.6	2.6	- ve	- ve	- ve
34	4953	58/M	8200	58	37	5	0	14	28	104	135	16	0.6	4.6	- ve	- ve	- ve
35	3958	50/F	7500	60	40	4	2	7	14	105	120	30	0.9	4.2	- ve	- ve	- ve
36	3985	54/F	6200	52	39	6	3	8	16	90	110	0.7	21	0.7	- ve	- ve	- ve
37	4019	47/F	7600	55	39	5	1	4	16	88	106	15	0.4	3.6	- ve	- ve	- ve
38	4017	32/F	4100	69	30	1	0	8	16	108	125	22	0.6	5.1	- ve	- ve	- ve
39	4046	52/F	7200	62	34	3	1	8	16	82	100	23	0.7	5.3	- ve	- ve	- ve
40	4078	55/F	8200	60	20	20	0	6	8	104	121	17	0.6	5.9	- ve	- ve	- ve

LAB INVESTIGATIONS BEFORE TREATMENT

Sno	OP/IP No	Age/Sex	Total Billirubin mg/dl	Direct. Billirubin mg/dl	ID. Billirubin mg/dl	SGOT IU/l	SGPT U/l	SAP U/l	T.Protein gm/dl	Albumin gm/dl	Globulin gm/dl	Calcium mg/dl	Phosphorous mg/dl
1	C80468	55/F	0.6	0.2	0.4	10	12	345	7.1	5.0	2.1	8.3	3.0
2	C80519	38/F	0.9	0.3	0.6	10	12	211	6.7	4.1	2.6	9.3	3.2
3	C78091	42/F	0.6	0.2	0.4	11	13	138	6.7	3.2	3.5	11.0	2.6
4	C73170	58/M	0.7	0.2	0.5	20	21	143	6.7	4.8	1.9	10.2	3.4
5	C42985	43/M	1.3	0.5	0.8	32	35	223	6.4	3.7	2.7	2.7	4.0
6	C40346	32/F	0.6	0.2	0.4	36	44	229	6.6	4.9	1.7	10.3	5.7
7	C53913	52/F	0.7	0.3	0.4	17	19	189	6.3	4.9	1.4	11.2	3.8
8	C31928	40/F	0.4	0.2	0.2	08	10	178	6.6	4.8	1.8	10.5	6.9
9	C66825	45/F	0.6	0.2	0.4	18	20	199	6.9	4.9	2.0	11.0	3.5
10	C14089	45/F	0.8	0.3	0.5	15	18	188	6.6	4.5	2.1	10.3	3.9
11	C82185	48/F	0.6	0.2	0.4	20	28	198	6.9	3.2	3.7	9.5	2.5
12	C61182	39/F	0.6	0.2	0.4	20	21	194	7.0	3.4	3.6	11.5	3.3
13	C81090	36/F	0.6	0.2	0.4	16	19	197	7.0	5.1	3.1	11.0	3.1
14	C40799	44/F	0.7	0.2	0.2	12	14	168	7.0	4.9	2.1	11.0	3.6
15	C23304	53/F	0.5	0.2	0.3	24	25	186	6.5	5.0	1.5	10.0	3.2
16	C78695	54/F	0.5	0.2	0.3	32	36	158	6.8	3.8	3.0	10.1	3.2
17	C80538	58/F	0.8	0.3	0.5	27	28	290	7.0	5.0	2.0	11.0	4.7
18	C10440	40/F	0.4	0.2	0.2	17	18	176	5.8	3.8	2.0	10.0	3.6
19	C52539	55/F	0.4	0.2	0.2	16	17	156	7.1	5.0	2.1	10.3	3.0
20	C73713	60/M	0.7	0.4	0.3	20	23	137	6.8	4.7	3.9	9.8	4.0
21	C83683	48/M	0.5	0.2	0.3	27	29	158	6.6	3.9	2.7	10.0	3.0
22	C 3464	60/F	0.8	0.3	0.5	21	22	162	6.0	4.0	2.0	11.0	3.6
23	C61756	60/F	0.6	0.2	0.4	20	21	213	6.5	4.0	2.5	11.4	3.6
24	C73565	60/F	0.5	0.3	0.2	19	20	139	6.5	4.1	2.4	10.0	2.9
25	B20623	52/F	0.5	0.2	0.3	28	29	166	5.0	3.0	2.0	11.0	3.6
26	C81675	39/F	0.4	0.2	0.2	19	20	180	7.1	4.0	3.1	9.9	3.0
27	C83165	45/M	0.4	0.2	0.2	26	39	291	6.9	3.9	3.0	9.8	3.0
28	C85803	60/M	0.6	0.3	0.3	16	17	155	7.0	4.0	3.0	10.6	3.1
29	C72639	45/M	0.6	0.3	0.3	14	15	199	7.0	5.0	2.0	10.1	2.9
30	C85465	42/M	0.7	0.3	0.4	20	21	166	6.4	4.0	2.4	10.3	3.0
31	4878	58/M	0.4	0.3	0.1	21	18	140	8.0	4.1	3.9	10.6	4.5
32	4958	60/M	0.9	0.5	0.4	17	15	204	6.6	3.7	2.9	10.1	3.3
33	4911	55/M	0.6	0.3	0.3	29	27	156	6.7	3.9	2.8	9.3	4
34	4953	58/M	0.5	0.3	0.2	19	16	196	7.0	3.9	3.1	10.1	3.6
35	3958	50/F	0.5	0.2	0.3	35	20	210	6.5	4.6	1.9	9	3.4
36	3985	54/F	0.7	0.4	0.3	25	19	235	8.3	5.3	3	10.6	8.3
37	4019	47/F	0.5	0.2	0.3	25	26	170	6.8	4.2	2.6	10.1	3.2
38	4017	32/F	0.5	0.3	0.2	21	19	296	8.3	4.3	4	8.3	3.7
39	4046	52/F	0.7	0.4	0.3	21	19	269	6.7	3.6	3.1	8.8	3.4
40	4078	55/F	0.4	0.2	0.2	26	28	176	6.6	4.1	2.5	10.0	3.0

LAB INVESTIGATIONS AFTER TREATMENT

Sno	OP/IP No	Age/Sex	Total Billirubin mg/dl	Direct. Billirubin mg/dl	ID. Billirubin mg/dl	SGOT IU/l	SGPT U/l	SAP U/l	T.Protein gm/dl	Albumin gm/dl	Globulin gm/dl	Calcium mg/dl	Phosphorous mg/dl
1	C80468	55/F	0.4	0.2	0.2	46	33	171	8.5	4.5	4	10.8	3.3
2	C80519	38/F	0.6	0.3	0.3	23	30	178	8	4.4	3.6	9.5	3.2
3	C78091	42/F	0.7	0.4	0.3	22	20	190	7.7	4.1	3.6	10	4
4	C73170	58/M	0.9	0.5	0.4	18	20	156	11.5	4.5	3	7.8	4.2
5	C42985	43/M	0.9	0.6	0.3	33	20	182	8	4.3	3.7	9.2	4
6	C40346	32/F	0.8	0.5	0.3	28	29	180	7.9	4.5	3.4	9	4.2
7	C53913	52/F	0.8	0.5	0.3	34	36	170	7.2	4.7	2.5	10.6	3.5
8	C31928	40/F	0.6	0.4	0.2	25	26	253	8	5.1	2.9	8.6	4.1
9	C66825	45/F	0.6	0.3	0.3	23	16	179	7.6	4	3.6	8	4.5
10	C14089	45/F	0.5	0.4	0.1	15	22	138	7.2	4.1	3.1	9.1	4.3
11	C82185	48/F	0.7	0.5	0.2	15	20	203	8.1	5	3.1	9.1	3.4
12	C61182	39/F	0.6	0.3	0.3	21	17	194	7	4.9	2.1	9.6	4.2
13	C81090	36/F	0.6	0.3	0.3	22	19	153	8.1	4.1	4	9.7	4.3
14	C40799	44/F	0.6	0.3	0.3	27	30	184	7.8	4.1	3.7	8.1	3.8
15	C23304	53/F	0.7	0.5	0.2	29	25	190	7	3.5	3.5	8.2	4.1
16	C78695	54/F	0.5	0.3	0.2	13	17	169	7.9	4	3.9	10.1	4.5
17	C80538	58/F	0.5	0.3	0.2	15	21	186	6.9	3.5	3.4	9.6	3
18	C10440	40/F	0.5	0.3	0.2	19	23	227	8	4.5	3.5	9.6	4.5
19	C52539	55/F	0.6	0.3	0.3	32	27	280	7	5	2	10.6	5.7
20	C73713	60/M	0.8	0.5	0.3	39	35	170	7.6	3.9	3.7	9.6	3.3
21	C83683	48/M	0.7	0.4	0.3	20	18	210	7.9	4.1	3.8	10	4.2
22	C 3464	60/F	0.8	0.5	0.3	40	34	189	8	4.3	3.7	9.5	4
23	C61756	60/F	0.6	0.4	0.2	25	20	165	7.8	4.6	3.2	10.4	3.9
24	C73565	60/F	0.7	0.4	0.3	24	26	215	7.8	4.2	3.6	10.3	3.5
25	B20623	52/F	0.5	0.3	0.2	20	22	147	8.2	5.6	2.6	9.3	3.6
26	C81675	39/F	0.6	0.4	0.2	28	25	280	7.6	4.8	2.8	9.6	3.8
27	C83165	45/M	1	0.5	0.5	30	29	200	7.6	3.8	3.8	9.6	3.6
28	C85803	60/M	0.8	0.4	0.4	21	18	144	6.9	3.7	3.2	9.6	3.5
29	C72639	45/M	0.7	0.4	0.3	20	14	206	6.8	5.3	1.5	10.3	3.7
30	C85465	42/M	0.7	0.5	0.2	20	25	180	8	5	3	9	4.4
31	4878	58/M	0.6	0.3	0.3	21	13	295	3.3	4.9	3.4	9.6	4.2
32	4958	60/M	0.7	0.4	0.3	20	19	172	6.3	4.3	2	9.6	4.6
33	4911	55/M	0.6	0.3	0.3	34	30	236	6.7	4.7	2	9.3	3.3
34	4953	58/M	0.7	0.4	0.3	26	18	190	7	3.9	3.1	10	3.8
35	3958	50/F	0.8	0.5	0.3	32	28	250	7	3.8	3.2	9.2	3.4
36	3985	54/F	0.8	0.5	0.3	27	20	235	8	5	3	10.4	3.3
37	4019	47/F	0.5	0.2	0.3	17	19	159	5.9	3.6	2.3	10.8	2.9
38	4017	32/F	0.7	0.5	0.2	27	25	280	6.2	4.7	2.5	10.3	4.7
39	4046	52/F	0.7	0.4	0.3	23	20	272	6.7	3.6	3.1	9	3.6
40	4078	55/F	0.6	0.3	0.4	10	12	216	6.9	3.5	3.4	10.4	3.0

URINE AND MOTION INVESTIGATIONS

S. NO	OP/IP NO	URINE												MOTION					
		Before Treatment						After Treatment						Before Treatment			After Treatment		
		Alb	Sug	Deposits		BS	BP	Alb	Sug	Deposits		BS	BP	Ova	Cyst	Occult bld	Ova	Cyst	Occult blood
				Pus Cells	Epi. cells					Pus cells	Epi. cells								
1.	C80468	NIL	NIL	2-4	1-3	NIL	NIL	NIL	NIL	2-5	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
2.	C80519	NIL	NIL	4-5	2-3	NIL	NIL	NIL	NIL	1-3	1-3	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
3.	C78091	NIL	NIL	2-4	2-5	NIL	NIL	NIL	NIL	2-4	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
4.	C73170	NIL	NIL	2-3	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
5.	C42985	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
6.	C40346	NIL	NIL	4-5	4-5	NIL	NIL	NIL	NIL	0-4	1-5	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
7.	C53913	NIL	NIL	2-3	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
8.	C31928	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	0-1	0-4	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
9.	C66825	NIL	NIL	2-4	1-2	NIL	NIL	NIL	NIL	1-2	1-4	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
10.	C14089	NIL	NIL	4-5	1-2	NIL	NIL	NIL	NIL	1-4	1-3	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
11.	C82185	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	0-1	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
12.	C61182	NIL	NIL	2-3	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
13.	C81090	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
14.	C40799	NIL	NIL	1-4	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
15.	C23304	NIL	NIL	2-4	1-3	NIL	NIL	NIL	NIL	2-4	1-3	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
16.	C78695	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	0-1	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
17.	C80538	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
18.	C10440	NIL	NIL	12	2-4	NIL	NIL	NIL	NIL	0-1	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
19.	C52539	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
20.	C73713	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	2-4	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL

URINE AND MOTION INVESTIGATIONS

S. NO	OP/IP NO	URINE												MOTION					
		Before Treatment						After Treatment						Before Treatment			After Treatment		
		Alb	Sug	Deposits		BS	BP	Albumin	Sugar	Deposits		BS	BP	Ova	Cyst	Occult bld	Ova	Cyst	Occult blood
				Pus Cells	Epi. Cells					Pus Cells	Epi. Cells								
21.	C83683	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	2-4	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
22.	C 3464	NIL	NIL	3-5	2-4	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
23.	C61756	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
24.	C73565	NIL	NIL	2-3	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
25.	B20623	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
26.	C81675	NIL	NIL	4-5	4-5	NIL	NIL	NIL	NIL	1-3	1-5	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
27.	C83165	NIL	NIL	2-3	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
28.	C85803	NIL	NIL	1-2	2-4	NIL	NIL	NIL	NIL	0-1	0-4	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
29.	C72639	NIL	NIL	2-4	4-5	NIL	NIL	NIL	NIL	1-2	1-5	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
30.	C85465	NIL	NIL	4-5	4-5	NIL	NIL	NIL	NIL	1-4	4-5	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
31.	4878	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	0-1	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
32.	4958	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
33.	4911	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
34.	4953	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
35.	3958	NIL	NIL	2-4	2-4	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
36.	3985	NIL	NIL	2-4	2-4	NIL	NIL	NIL	NIL	0-1	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
37.	4019	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
38.	4017	NIL	NIL	1-2	1-3	NIL	NIL	NIL	NIL	0-1	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
39.	4046	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	1-2	0-1	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
40.	4078	NIL	NIL	1-2	1-2	NIL	NIL	NIL	NIL	2-4	1-2	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL

Discussion

DISCUSSION

Azhal keel vayu is a disease characterized by pain and swelling in knee joints, morning stiffness, tenderness, crepitations, restricted movements and low grade fever. The signs and symptoms of Azhal keel vayu as per Sapabathy kaiyedu and siddha maruthuvam pothu can be correlated with Osteoarthritis in Modern science.

- The aim of the study is to evaluate the therapeutic efficacy of sarva noi linga chenduram (internal) and Maasha thylum (external) in the treatment of Azhal keel vayu.
- The protocol has been approved by Institutional Animal Ethical committee (IAEC) and Institutional Ethical committee.(IEC) in NIS,Chennai IEC/NIS/2011/3/03
- The required raw drugs for preparation of Sarva noi linga chenduram and Maasha thylum were authenticated by Asst.Prof of Medicinal Botany National Institute of Siddha. The drugs were purified and medicine was prepared in Gunapadam laboratory of National institute of siddha.
- The biochemical (both Qualitative and Quantitative analysis) and toxicological studies of the trial drug Sarva noi linga chenduram were doneNIS and IIT, Chennai.
- Toxicological studies of the trial drug Sarva noi linga chenduram was done in the of pharmacology lab , National Institute of Siddha and the results were documented.
- The present clinical study was done as per the approved protocol and the data were collected by using the prescribed proforma from the 40 cases who were treated in the inpatient ward and outpatient department of Maruthuvam.
- The patients were treated for a period of 48 days with Sarva noi linga chenduram (internal medicine) at the dose of 130 mg, twice a day with the adjuvant of honey and Maasha thylum (external medicine) for external application.

Clinical assessment was done during each visit in OPD patients (12 days once) and daily for IPD patients and the data were noted in the prescribed proforma

The observations discussed below:

Gender distribution:

The majority affected sex was female i.e, 28 cases (70%). The common cause for this may be depletion of calcium from their body due to menopause and increased house hold works.

Age distribution:

This study showed that the highest incidence of Azhal keel vaayu was between 50 – 60 years of age, i.e 23 cases (57.5%), and 40-50 years of age 11 cases (27.5%) because degeneration starts from this age.

Gunam:

All the 40 cases under this analysis were predominantly of Rajo gunam assessed from interrogation and other observations.

Kaalam distribution:

Among the 40 cases, 38 cases(95%) were found to be in pitha kaalam (34-66 yrs) and only 2 cases (5%) were found in the vaatha kaalam.

Diet:

Among the 40 cases 32 cases (80%) were non-vegetarians. Non vegetarian diet may be the cause for accumulation of fat and there by promoting obesity. This altered the weight transferring mechanism in knee joints, causing this disease.

Thinai distribution;

In this study, 77.5% of cases were reported from Neithal land.

In Siddha literatures, it was mentioned that Neithal is a land, which is responsible for vaatha diseases. This study also emphasized the same.

Socio Economic Occupational references:

Home maker accounts for the highest number of 23 cases (57.5%). More weight bearing, improper positioning of knee also produces the impact**.**

Precipitating factors:

Already it was explained that aging is the most common cause for Azhal keel vaayu. Apart from that, menopause (55%), increased household works (50%), Obesity (30%), occupational related (42.5%) are the precipitating factors.

Clinical features:

Pain in the knee joint present in the 40 cases, morning stiffness were present in the 13 cases(32.5%) crepitation in the 22 cases(55%), and restricted movements were present in almost all the 37 cases (92.5%). Swelling was present in 28 cases (70%), 15 cases (37.5%) had tenderness, 12 cases (30%) had warmth and only one cases had Genuvarum deformity in affected knee joints.

Kanmenthiriyam:

Kaal was affected in all the 40 cases (100%) due to difficulty in walking. 23 cases (57.5%) were improved after the treatment.

Derangements noted in vatham:

In all the 40 cases observed ,viyanan and samanan were affected in all the 40 cases(100%) due to difficulty in movements of knee joints , abanan was affected in 4 cases(10%) due to constipation, koorman was affected in 11cases(27.5%) due to diminished vision owing to age, kirugaran was affected in7 cases,(17.5%) due to loss of appetite and thevathaththan was affected in 6 (15 %) cases due to sleeplessness.

Derangement noted in pitham:

Out of 40 cases, saathaga piththam was affected in almost almost all the cases (100%) due to difficulty in walking, anarpitham was affected in 12cases (30%) due to loss of appetite, alosagam was affected in 19 cases (47.5%) due to diminished vision owing to age and Ranjaka piththam was affected in 8 cases (20%) due to pallor.

4 cases were improved from their previous haemoglobin level after the treatment.

Derangement of kabam:

Santhigam was affected in all the 40 cases. Santhiga kabam mainly lives in joints and so it was affected in all the cases. 34 cases were improved from their walking difficulty after the treatment.

Udal thathukkal:

Among the 7 udal kattugal, Saaram, Enbu, kozhuppu and moolai were affected in all the 40 cases (100 %) due to weakness, pain and morning stiffness occurs in affected knee joints. Oon was affected in 28 cases (70%) due to swelling in affected in knee joints. Senneer was affected in 8 cases (20%) due to pallor and reduction in haemoglobin level.

40 cases were improved from their pain, 11 cases (27.5%) were improved from their morning stiffness, 21cases improved from swelling (52.5%) after the treatment.

Ennvagai thervugal:

Almost all cases affected were examined by the Ennvagai thervugal observations.

Pulse reading (Naadi) was observed in all patients. 24 cases(60%) had Vathapitham, 7 cases (17.5%) had Pithavatham, 2 cases had Pithakabam and 6 case had vatha kabam. Malam was affected in 4 cases(10%) due to constipation and vizhi was affected in 8 cases(20%) due to pallor, sparisam was affected in 12 cases(30%) due to warmth over the affected knee joints

Derangement of Kosangal

Among the 40 cases , annamaya kosam was affected in 7 cases(25 %) resulted in loss of appetite, manomaya kosam was affected in 14 cases(35 %) resulted in depression, and vignanamaya kosam was affected in 40 cases (100 %) resulted in pain in knee joints.

Neikkuri:

In 11 cases (27.5) oil was lengthening like a snake i.e, Aravena neendathu which indicates vaatha neer and in 29 cases (72.5%) it appeared like a pearl i.e, Muthu pol nindrathu which indicates kabaneer.

Laboratory investigations:

Laboratory investigation of blood, urine, stools and x-ray were done for all 40 cases. In laboratory investigations anaemia was found in 6 cases. ESR was found raised during study enrollment and after treatment it was found reduced. There were remarkable changes in ESR, TRBC and Haemoglobin.

Blood Urea, serum Creatinine levels have not shown much remarkable changes.

Radiological investigation

The radiographic studies showed narrowed joint space and presence of Osteophytes in all 40 cases(100%). No radiographic changes observed after treatment.

Outcome :

Primary out come.

Nature of pain- Pain assessment scale

- Before treatment mild pain was present in 14(35%) cases, moderate pain was present in 19(47.5%) cases, and severe pain was present in 7 (17.5%) cases.

- After treatment with the trial medicine Sarva noi linga chenduram(Int) and Maasha thylum(External) for 48 days, no pain was present in 23 cases (57.5%) mild pain was present in 6(15%) cases, moderate pain was present in 7(17.5%) cases.

On the basis of effect of the trial drugs, Good improvement was assessed in 23 cases(57.5%), moderate improvement in 11 cases(27.5%) and mild improvement in 6 cases(15%).

Secondary outcome:

Clinical features:

Among the 40 cases, all the 40 cases (100%) had Pain, 13 cases932.5%) had morning stiffness, 22 patients had crepitation(55%), restricted movements in 37 patients(92.5%) in their affected knee joints. 28 cases (70 %) had swelling, 12 cases(30%) had warmth, 15 cases (37.5 %) had tenderness, 4 cases (10%) had instability and only one patient had Genu varum deformity. During each visit the clinical symptoms were assessed and observations were recorded in the prescribed proforma.

After treatment with the trial medicine Sarva noi linga chenduram, (Internal)&Maasha thylum (external) for 48 days, 23 cases had relieved from pain, 21 cases had relieved from swelling, 8 cases had relieved from warmth, 10 cases had relieved from tenderness, 11 cases had relieved from morning stiffness, 3 cases had relieved from instability, 27 cases had relieved from restricted movements.

Biochemical analysis:

Qualitative analysis of Sarva noi linga chenduram reveals that the trial medicine contains the following elements.

- Calcium
- phosphate
- Carbonate
- Iron
- Aluminium
- Magnesium
- Mercury
- Silicate
- Sodium
- Unsaturated Compunds

TOXICITY STUDIES

* **Acute oral toxicity study:** [WHO guidelines, 1993]

Sarva noi linga chenduram at the dose of 4.68mg/kg/bw did not exhibit any mortality in mice. In Necropsy ,the organs of the animal such as, Liver, Heart, Lungs, pancreas Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

* **Sub acute toxicity study:** [WHO guidelines, 1993]

Sarva noi linga chenduram at the dose of 23.4/kg/bw(10x) did not exhibit any mortality in rats. Biochemical parameters and histopathology report were also normal. There were no signs of toxicity.

SUMMARY

SUMMARY

- The aim of the study was to evaluate the efficacy of the drug SARVA NOI LINGA CHENDURAM (Internal) and MAASHA THYLAM (External) in AZHAL KEEL VAYU

- Before initiating the clinical trial, approval was got from the Institutional Animal Ethical Committee and Institutional Ethical Committee for conducting the pre clinical studies and clinical studies respectively by submitting the well defined protocol and proforma.

- The raw drugs were authenticated by the concerned department and the trial drug was prepared by the investigator in the Gunapadam lab of National Institute of Siddha as per the Standard Operating Procedure mentioned in the protocol.

- The medicine was then subjected to pre clinical studies (Acute and sub acutr toxicity studies) as per the protocol and the safety of the drug was ensured.

- The qualitative and quantitative bio chemical studies were done at the bio chemistry lab of National Institute of Siddha and IIT Chennai respectively.

- Among the 60 cases screened at the OPD of department of Maruthuvam NIS, 40 cases were recruited for the trial as per the inclusion and exclusion criteria.

- Clinical diagnosis of Azhal keel vayu was made by Siddha and Modern methodology.

- Before inducement into the trial informed consent was obtained from the patients. Out of the 40 cases 30 cases were treated in OPD and 10 cases in IPD.

- A day before the trial drug administration, puragative medicine was given Agasthiyar kuzhambu 130mg given to correct the elevated Vatha thathu and bring's other the two deranged thathus to equilibrium.

- The trial medicines selected for both Internal and External treatment were SARVA NOI LINGA CHENDURAM 130 mg b.i.d with the adjuvant honey and MAASHA THYLUM referred under Siddha literature Anupoga Vaithiya Navaneetham IV part respectively.

    - ★ During the treatment period of 48 days the trial drug SARVA NOI LINGA CHENDURAM (Internal) is given for 7 days followed by a break (re dieting) of 5 days. Likewise the medicine is given till the end of the course as given in Siddha Literature.

    - ★ Every first day of the break (re dieting) started with head bath with the paste of Ajowan seeds with cow's milk as indicated in Siddha text.

- Diet restriction was strictly followed during the period of drug administration as well as re dieting period (Diet free of salt, tamarind etc) as per noted in the form IV E (Dietary advice form).
- Required lab investigations were carried out before and after the treatment and the concerned data was recorded in the proforma.
- Clinical assessment was done daily in all the IP patients and in OP patients it was assessed once in 12 days.
- The study Results showed that 57.5 % had good improvement 22.5 % had moderate improvement 15 % had mild improvement.
- As per the Siddha Literature and modern science reviews and research articles, the ingredients of the trial drugs were found to have the property of controlling the Vatha diseases, some drugs exhibited anti inflammatory and analgesic action owing to the disease manifestations.
- During the study period, there was no event of any adverse reactions owing to the drug or disease.
- Radiological investigation (X ray knee joint- AP & LAT VIEW) was also done before and after treatment.
- Statistical analysis showed significant reduction in pain scale before and after the treatment. ($P < 0.001$) Statistical analysis on lab parameters also showed significant outcome.
- Oral toxicity studies conducted ensured the safety usage of the drug to animals up to a maximum dose of 23.4 mg/animal.
- Bio chemical analysis showed the presence of constituents like Calcium, Iron, Sulphur which played a role in repairing and preventing the joint damage in the disease. The minimum particle size (3 µ) unveiled in the (Particle Per Million size) PPM analysis shows the existence of the drug in micro particle size which contributes its therapeutic effect by the increased bio availability.

CONCLUSION

CONCLUSION

AIM

The principal aim of the present study is

- ✓ To evaluate the therapeutic efficacy of the Siddha formulations Sarva noi linga Chenduram (Internal) and Maasha thylam (External) in the treatment of Azhal keel vayu (Osteo arthritis).

OBJECTIVES

PRIMARY OBJECTIVE

- ✓ To evaluate the therapeutic efficacy of the Siddha drugs sarva noi linga Chenduram (Internal) and Maasha thylum (External) in reducing the pain in Azhal keel vayu (Osteo arthritis).

SECONDARY OBJECTIVE

- To conduct a clinical trial with a well defined proforma on the patients identified with "Azhal keel vayu ".
- To evaluate the safety of the test drugs (Acute and Sub acute toxicity studies) to be carried out as per WHO guidelines.
- To study the influence of other co factors such as age, sex, dietary habits, family history, socio economic status, habitat etc on the disease.
- To study Azhal keel vayu on the basis of

  (a) Mukkutram (b) Udalkattugal (c) Envagai thervugal etc
- To find out the side effects / adverse effects of the drug "SARVA NOI LINGA CHENDURAM (Internal) and MAASHA THYLUM (External)" if any.
- To screen the biochemical constituents of the drug.

- Toxicity study reveals that the trial drug is safe in acute and sub acute toxicitiy even in higher dosage of 46.8 mg/ animal in albino rats as per WHO guideliness 1993.
- Clinical results showed to be Good improvement in 57.5% of cases, moderate improvement in 15% cases and mild improvement in 27.5% of cases.
- There is significant difference between pain assessment scale of before and after treatment ($P < 0.001$)
- During the course of the treatment adverse drug reactions were not found.
- The results of the clinical trail indicates that the trail drugs are clinically effective, safe and also economical.
- Because of the encouraging clinical and laboratory results, the study may be extended with the same drug in more number of cases, in treating Azhal keel vayu successfully.

ANNEXURE I

Toxicological studies

ACUTE TOXICITY STUDY OF SARVA NOI LINGA CHENDURAM

[WHO guidelines, 1993]

Principle:

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound. The study duration was 14 days.

Animal species **:** Swiss albino mice

Age / Weight / Size **:** 6 weeks. Mice-20-25 gms.

Gender **:** Both male and female

Number of Animals **:** Mice: 20

Acclimatization Period **:** 7 Days

Clinical dose **:** 130mg\day

S.No	Group	No of mice
1	Vehicle control	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose (2.34mg)	10 (5 male, 5 female)

Test Animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at Animal house, National institute of Siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c).The animals had free access to water and standard pellet diet (Sai meera foods pvt.ltd, Bangalore).The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. **(1248/ac/09/CPCSEA/December/IAEC 2011)**

Route of administration:

Oral route was selected, because it is the normal route of clinical administration.

Test substance and vehicle

SARVA NOI LINGA CHENDURAM is brick red in colour .The test substance was insoluble in water. In order to obtain and ensure the uniformity in drug distribution, the drug was dissolved by Normal solution (10%).

Administration of doses:

Sarva noi linga Chenduram was suspended in aqueous normal saline solution (10%), with uniform mixing and it was administered to the group's in a

single oral dose. The control groups received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 130 mg\day. It was converted to animal dose (2.34 mg) and then administered. The principle of laboratory animal care was followed.

Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. Animals were observed individually. Visual observations included skin changes, alertness, grooming, aggressiveness, sensitivity to sound, touch and pain, restlessness, tremors, convulsion, righting reflex, gripping reflex, pinna reflex, corneal reflex, writhing reflex, papillary reflex ,urination, salivation, lacrimation for first 4 hrs, then periodically during the first 24 hrs. Animals were observed for body weight and mortality for 14 days. If animals dye during the period of study, the animals were sacrificed. At the end of the 14^{th} day all animals were sacrificed and necroscopy was done.

Body Weight

Individual weight of animals were determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test surviving animals were weighed and sacrificed.

Results: Sarva noi linga Chenduram at the dose 2.34mg/animal did not exhibit any mortality in mice.

No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

SUB ACUTE TOXICITY STUDY OF SARVA NOI LINGA CHENDURAM

[WHO guidelines, 1993]

Animals	**:**	Male and Female Wister albino rats
Age	**:**	6-8 weeks
Weight	**:**	150-200 gms
Gender	**:**	Both male and female
Number of animals	**:**	Rat: 40
Acclimatization period	**:**	28 Days
Clinical dose	**:**	260mg\day
Clinical duration	**:**	28 days

S.No	Group	No of Rats
1	Vehicle control	10 (5male,5 female)
2	1XTherapeutic dose (4.68 mg)	10 (5male,5 female)
3	5XTherapeutic dose (23.4mg)	10 (5male,5 female)
4	10XTherapeutic dose(46.8mg)	10(5male, 5 female)

Animal source:

Test animals were obtained from the animal laboratory of the King institute, Chennai, and stocked at national institute of siddha, chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c) .The animals had free access to water and standard pellet diet (Sai durga foods pvt.ltd, Bangalore). The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. **(1248/ac/09/CPCSEA/December/IAEC 2011)**

Identification of animal:

By cage number, animal number and individual marking on fur.

Housing and Environment:

The animals were housed in polypropylene cages provided with bedding of husk .Dark and light cycle each of 12 hours.

Administration period:

The period of administration of the test substance to animals are depending on the expected period of clinical use. Since the clinical duration of the test drug is 28 days and as per WHO guidelines the administration period is reported to be 1 month.

Dose selection:

The results of acute toxicity studies in Swiss albino mice indicated that Sarva noi linga chenduram was non toxic and no behavioral changes, mortality was observed. On the basis of these results, the doses were selected for the study as per WHO guidelines.

Preparation and administration of dose:

Sarva noi linga chenduram was suspended in saline solution.It was administered to animals at dose levels of 1Xtherapeutic dose (4.68mg/animal), 5XTherapeutic dose (23.4mg/animal) and 10XTherapeutic dose (46.8mg/animal).The control animals were administered vehicle only. Administration was by oral (gavage) once a day for 30 days.

METHODOLODY:

Randomization, numbering and grouping of animal:

The animals were randomly divided into three groups for dosing up to 30 days. Each group consist of 10 animals (5 per sex in each group) were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal fur was marked with picric acid. The females were nulliparous and non pregnant.

OBSERVATION:

Experimental animals were kept under observation throughout the course of study for the following.

Body weight:

Weight of each rat was recorded on day 1 and at weekly intervals throughout the course of study and at termination to calculate relative organ weights. From the data mean body weights and percent body gain were calculated.

Food and water consumption:

The quantity of food consumed by groups consisting of an animal for different doses was recorded at weekly intervals. Food consumed per animal was calculated for control and the treated dose groups

Clinical sings

All animals were observed daily for clinical sings. The time of onset intensity and duration of this symptom if any were recorded

Mortality:

All animals were observed twice daily for mortality during entire course of study.

TERMINAL STUDIES:

LABORATORY INVESTIGATIONS:

Following laboratory investigations were carried out. On day 31 animals fasted_overnight .Blood samples were collected by cardiac puncture using sodium heparin (200IU\ml) for blood chemistry and potassium EDTA (1.5 mg/ml) for hematology anticoagulant. Blood sample were centrifuged at 3000 r. p .m for 10 minutes.

Biochemical investigations:

The effect of **Sarva noi linga chenduram** on certain biochemical parameters were examined and compared with those of the control group. The blood samples collected with heparinized bottles were centrifuged at 5000 rpm for 10 minutes to obtain clear serum for the following investigation. Glucose was estimated using commercial Glucose estimation kit (Span Diagnostics) by the method of Barham *et al.,* (1972) and Tenscher. *et al.,* (1971),Haemoglobin PCV, RBC, Erythrocyte count was estimated by Hemocytometer method of Ghai (1995). Total Leukocyte Count was estimated by Hemocytometer method of John (1972).Total, (Bilirubin test kid-malloy and evelyn 1937) direct and indirect bilirubins were determined. Alkaline phosphatase, Alanine amino tranferase (ALT) and Aspartate amino transferase (AST) were measured by using ALT and AST test kit (kind & king) .Total protein TP concentration was determined. Albumin was determined based on its reaction with bromocresol green (binding method) .Urea was determined according to urease –berthelot method and plasma creatinine was estimated using jaffe reaction. Results of biochemical investigations conducted on day 31 revealed significant

changes in the values of different parameters studied when compared with those of respective controls.

NECROPSY:

All the animals were sacrificed on day 31 under ether anesthesia. Necropsy of all animals was carried out and the weights of the organs including liver, kidneys, brain, heart, and lungs were recorded.

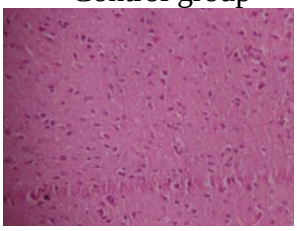
HISTOPATHOLOGY:

Tissue samples of organs from control and treated animals were preserved in 10% formalin for preparation of sections using microtome. The organs included liver, kidneys, heart, lungs and stomach of the animals were preserved and they were subjected to histopathological examination.

The organ pieces (3-5 micron) were fixed in 10% formalin for 24 hours and washed in running water for 24 hours .Samples were dehydrated in tissue processor and then cleaned in benzene to remove absolute alcohol .Embedding was done by passing the cleared sample through three cups containing molten paraffin at 50 degree c and then a cubical block of paraffin made by the L moulds it was followed by microtome and the slides were stained with haematoxylin–eosin stain .Stained sections of each organ were examined under light microscope at high (40X) power magnification. All the histo pathological slides were prepared at Dept .of. Pathology,Vels university,pallavaram Chennai.

1.HISTO PATHOLOGY OF BRAIN.

Control group



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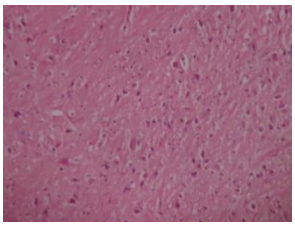

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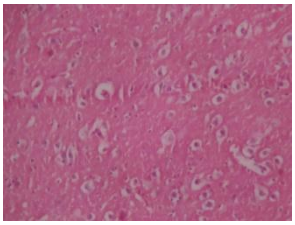

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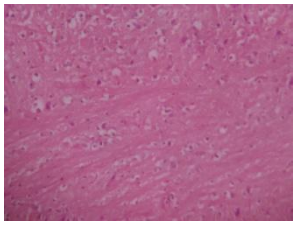
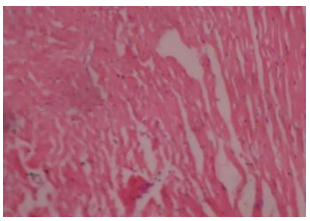


FIGURE.1

2.HISTO PATHOLOGY OF HEART

Control group



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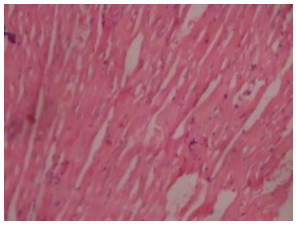

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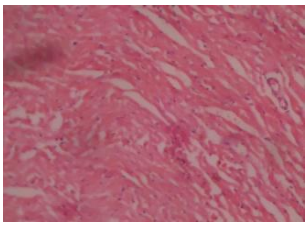

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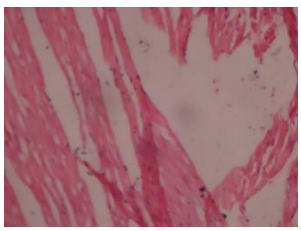
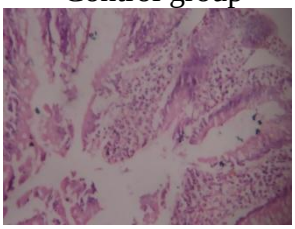


FIGURE.2

3.HISTOPATHOLOGY OF INTESTINE

Control group



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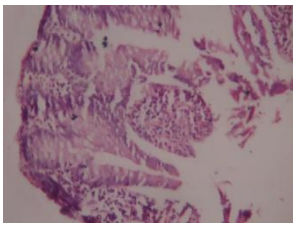

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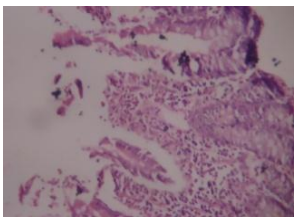
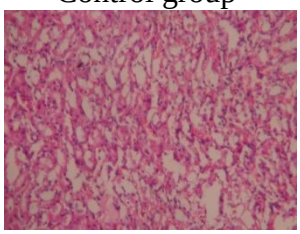


FIGURE.3

4.HISTOPATHOLOGY OF KIDNEY

Control group



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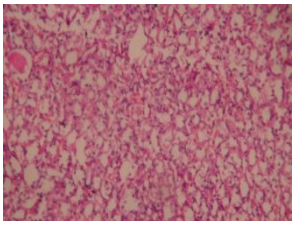

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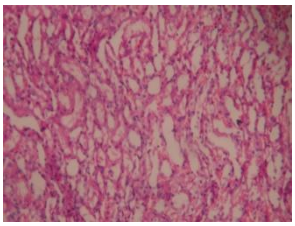

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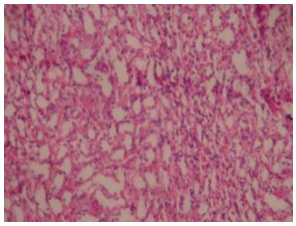
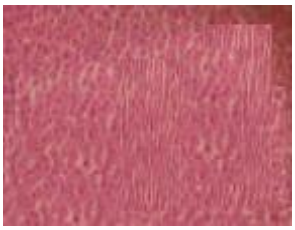


FIGURE.4

5.HISTO PATHOLOGY OF LIVER

Control group



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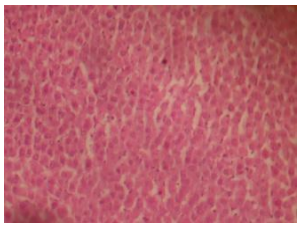

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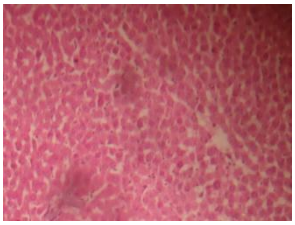

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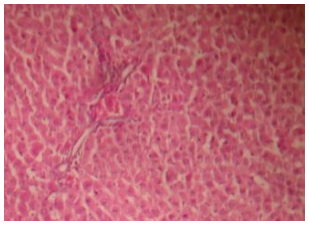
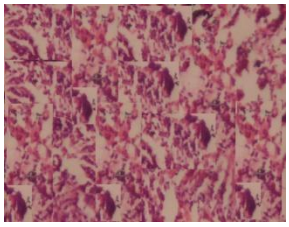


FIGURE.5

6.HISTO PATHOLOGY OF LUNG

Control group



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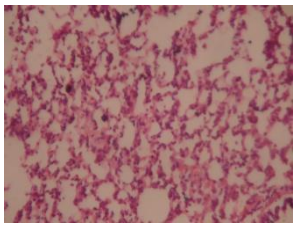

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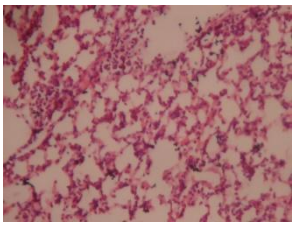


10x - C

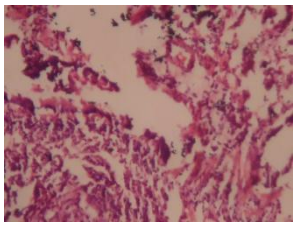
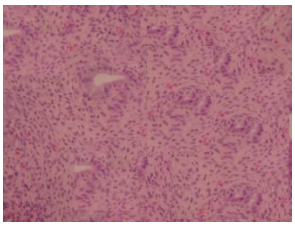


FIGURE.6

7.HOSTO PATHOLOGY OF OVARY

Control group



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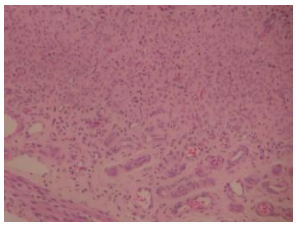

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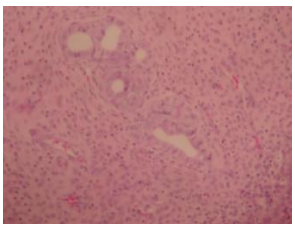

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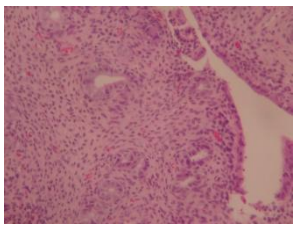
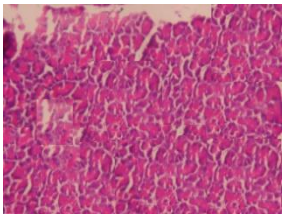


FIGURE.7

8.HISTO PATHOLOGY OF PANCREAS

Control group



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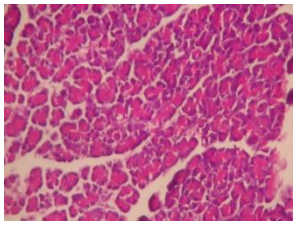

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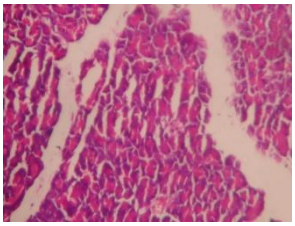

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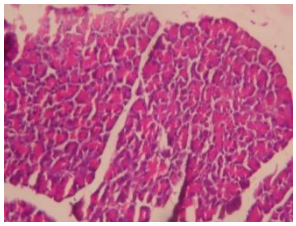
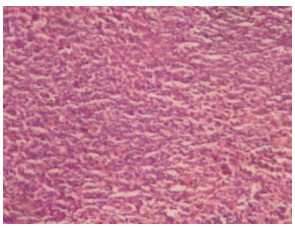


FIGURE.8

9.HISTO PATHOLOGY OF SPLEEN

Control group



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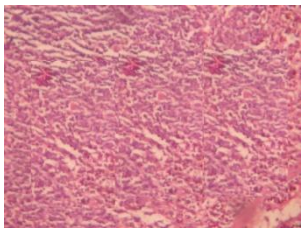

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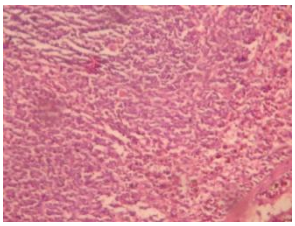

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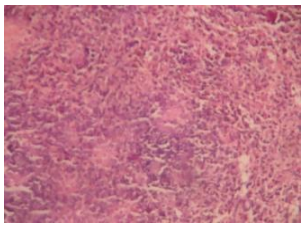
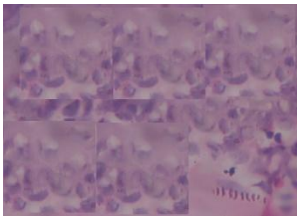


FIGURE.9

10. HISTOPATHOLOGY OF STOMACH

Control group



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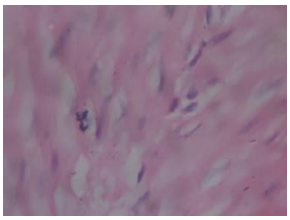

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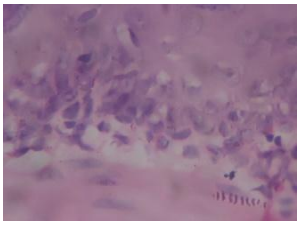

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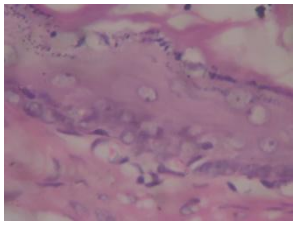
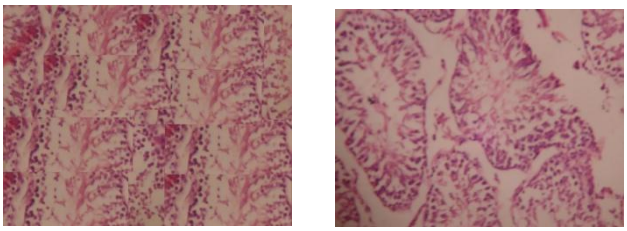


FIGURE.10

11.HISTO PATHOLOGY OF TESTIS

Control group 1x –A



5x –B 10x - C

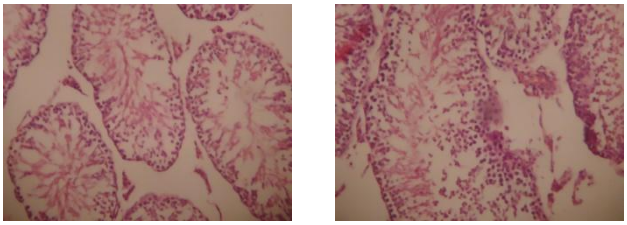


FIGURE.11

TREATED on control Group (Low dose)

Kidney: shows normal renal tissue with glomeruli and tubules.

Spleen: shows normal spleen with lymphoid aggregation.

Liver: shows almost normal hepatocytes and occasional binucleate cells.

Stomach: shows normal mucosal glands.

Ovary: shows ovarian stroma with follicles and corpus leuteum.

Lung: shows normal alveoli.

Testis: shows normal tubules with spermatogenesis.

Heart: shows normal cardiac muscle bundles.

Brain: shows normal brain with nerve fibers and astrocytes.

Intestine: Shows normal Intestinal mucosal lining with mild exudates.

Bone: Shows normal osteocytes

Pancreas: shows normal acini with islets of β-cells

IMPRESSION: NORMAL STUDY

Treated on 5x (Mid dose)

Brain:

shows brain with edema, microglial proliferation, shows brain with micro cystic change and astrocytic proliferation, shows brain with mononuclear infiltrate around vessel.

Kidney:

shows renal tissue with focal tubular damage, interstitial inflammatory collection. Glomeruli shows epithelial proliferation.

Liver:

shows hepatocytes with focal mild fatty change.

Spleen:

shows congestion with lymphoid hyperplasia.

Stomach:

shows near normal mucosal gland with mild exudates.

Lung:

shows congested alveolar wall with mild thickening and mild emphysematous changes.

Pancreas:

shows pancreas with acini and normal islets.

Testis:

shows normal tubules with spermatogenesis.

Heart:

shows congestion and mild inflammatory infiltration in between cardiac muscle bundles.

Ovary:

shows ovarian stroma with follicles and corpus leuteum.

Intestine:

Shows normal Intestinal mucosal lining with mild exudates.

Bone: Shows normal osteocytes

IMPRESSION: NORMAL STUDY

TREATED 10x (High dose)

Stomach: shows stomach with superficial erosion and congestion.

Heart: shows hypertrophic cardiac muscle bundles.

Spleen: shows lymphoid hyperplasia.

Brain: shows brain with edema. Astrocytes show degenerative changes.shows brain with pyknotic irregular nucleus, shows brain with vesicular nuclei and micro cystic changes.

Liver: shows marked dilatation of sinusoids, degeneration of hepatocytes, necrosis.

Kidney: shows renal tissue with tubular epithelial damage.

Pancreas: shows atrophic islet cells.

Testis: Giant cells were formed in the lumen of the seminiferous tubules and the spermatogenic cells degenerated. **Lung:** shows congestion, narrowed alveolar space and thickened alveolar wall.

Ovary: shows ovarian follicles and corpus leuteum.

Intestine: Shows normal Intestinal mucosal lining with mild exudates.

Bone: Shows normal osteocytes

IMPRESSION: NORMAL STUDY

Results:

* No weight loss, abnormal animal behaviours, metabolic functions [urination, lacrimation, defaecation etc.,] and mortality were noted.
* In necropsy of the animal organs showed normal appearance and weight.
* All Haematological and biochemical parameters were within normal limits.
* The stastical report of the Haematological and Biochemical datas did not show any significant difference, between the control and test groups.
* In Histopathological studies, No abnormal findings were observed in the organs such as Heart, Liver, Lungs, Kidney and Stomach in X, 5X and 10X compared with control group.

Annexure II

Bio Chemical Analysis

BIO -CHEMICAL ANALYSIS OF SARVA NOI LINGA CHENDURAM – ANALYSED AT NATIONAL INSTITUTE OF SIDDHA

Appearance of sample		**Red in colour**	
S. no	EXPERIMENT	OBSERVATION	INFERENCE
1.	**Solubility:** a. A little (500mg) of the sample is shaken well with distilled water. b. A little (500mg) of the sample is shaken well with con. HCl/Con. H_2So_4	Sparingly soluble	Presence of Silicate
2.	**Action of Heat:** A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.	White fumes evolved	Presence of Carbanate
3.	**Flame Test:** A small amount (500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared	Absence of copper
4.	**Ash Test:** A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited	Yellow colour flame appeared	Presence of Sodium

Preparation of Extract:

5gm of Sarva noi linga chenduram is weighed accurately and placed in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

I.Test For Acid Radicals			
S. no	**EXPERIMENT**	**OBSERVATION**	**INFERENCE**
1	**Test For Sulphate :** 2ml of the above prepared extract is taken in a test tube to this added 2ml of 4%dil. ammonium oxalate solution.	No cloudy appearance appeared	Absence of sulphate
2	**Test For Chloride:** 2ml of the above prepared extracts is added with 2ml of dil-HCl is added until the effervescence ceases off.	No cloudy appearance appeared	Absence of chloride
3	**Test For Phosphate:** 2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of con.HNO_3	Mild yellow appearance present	Presence of Phosphate
4	**Test For Carbonate:** 2ml of the extract is treated with 2mldil. magnesium sulphate solution	Cloudy appearance present	Presence of Carbanate
5	**Test For Fluoride & Oxalate:** 2ml of extract is added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated.	No cloudy appearance	Absence of fluoride and oxalate

6	**Test For Nitrate:** 1gm of the substance is heated with copper turning and concentrated H2SO4 and viewed the test tube vertically down	No brown gas evolved	Absence of nitarte
7	**Test For Sulphide:** 1gm of the substance is treated with 2ml of con. HCL	No Rotten Egg Smelling gas evolved	Absence of sulphide
8	**Test For Nitrite:** 3drops of the extract is placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil. Benzidine solution is placed.	No characteristic changes	Absence of Nitrite
9	**Test For Borate:** 2 Pinches (50mg) of the substance is made into paste by using dil.sulphuric acid and alcohol (95%) and introduced into the blue flame.	Bluish green colour flame not appeared	Absence Of Borate
II. Test For Basic Radicals			
1	**Test For Lead:** 2ml of the extract is added with 2ml of dil.potassium iodine solution.	No Yellow Precipitate is obtained.	Absence of lead
2	**Test For Copper:** One pinch (50mg) of substance is made into paste with con. HClin a watch glass and introduced into the non-luminuous part of the flame.	Blue colour precipitate formed.	Presence of Copper

3	**Test For Aluminium:** To the 2ml of extract dil.sodium hydroxide is added in 5 drops to excess.	Yellow colour appeared	Presence of Aluminium
4	**Test For Iron:** a. To the 2ml of extract add 2ml of thiocyanate ammonium solution b. To the 2ml of extract add 2ml of thiocyanate ammonium solution and 2ml of con HNO_3 .	Red colour appeared	Presence of iron
5	**Test For Zinc:** To 2ml of the extract dil.sodium hydroxide solution is added in 5 drops to excess and dil.ammonium chloride is added.	White precipitate is not formed	Absence of Zinc
6	**Test For Calcium:** 2ml of the extract is added with 2ml of 4% dil.ammonium oxalate solution	Cloudy appearance and white precipitate is obtained	Presence of Calcium
7	**Test For Magnesium:** To 2ml of extract dil.sodium hydroxide solution is added in drops to excess.	White precipitate is obtained	Presence Of Magnesium
8	**Test For Ammonium:** To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.	No Brown colour appeared	Absence of Ammonium

9	**Test For Potassium:** A pinch (25mg) of substance is treated off with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.	No yellowish precipitate is obtained	Absence of Pottasium
10	**Test For Sodium**: 2 pinches (50mg) of the substance is made into paste by using HCl and introduced into the blue flame of Bunsen burner.	Yellow colour flame appeared	Presence of sodium
11	**Test For Mercury**: 2ml of the extract is treated with 2ml of dil.sodium hydroxide solution.	Yellow precipitate is obtained	Presence of Mercury
12	**Test For Arsenic:** 2ml of the extract is treated with 2ml of dil.sodium hydroxide solution.	No Brownish red obtained	Absence of Arsenic
III.Miscellaneous			
1	**Test For Starch:** 2ml of extract is treated with weak dil.iodine solution	No blue colour devolopped	Absence of Starch
2	**Test For Reducing Sugar:** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted	Brick red colour not devolopped	Absence of reducing sugar

3	**Test For The Alkaloids:** a) 2ml of the extract is treated with 2ml of dil.potassium lodide solution. b) 2ml of the extract is treated with 2ml of dil.picric acid. c) 2ml of the extract is treated with 2ml of dil.phosphotungstic acid.	Yellow colour not developed	Absence of alkaloid
4	**Test For Tannic Acid:** 2ml of extract is treated with 2ml of dil.ferric chloride solution	No black precipitate obtained	Absence of Tannic acid
5	**Test For Unsaturated Compound:** To the 2ml of extract 2ml of diluted Potassium permanganate solution is added.	Potassium permanganate solution is decolourised	Presence of Unsaturated compounds
6	**Test For Amino Acid:** 2 drops of the extract is placed on a filter paper and dried well. 20ml of Biurette reagent is added.	Violet colour not developed	Absence of Aminoacid
7	**Test For Type Of Compound:** 2ml of the extract is treated with 2 ml of dil.ferric chloride solution.	No Brown colour developed	Absence of Oay quinole, Pinephrine and Pyro catechol

Table-1

- **Colour characters of Sarva Noi Linga Chenduram.**

S No	Solvent used	Under ordinary light	Under ultra violet light
1	**Powdered material**	**Dark Brown**	**Dark Brown**

Table-2

- **Physicochemical properties of Sarva Noi Linga Chenduram.**

S No.	Parameters	Values obtained (%w/w)	Heavy/ toxic metals	
1	Total ash value	9.15	Lead	BDL
2	Acid insoluble ash	0.77	Cadmium	BDL
3	Water soluble ash	5.63	Mercury	4.251mg/L
4	Moisture content	10.24	Arsenic	BDL

Table-3

- **Colour, nature and percent yields of extracts of Sarva Noi Linga Chenduram**

S.no.	Extract Solvents	Colour	Nature	% Yield(w/w)	SEM-Micro graph partical size range in micron	pH
1	Water	Dark brown	**Solid**	49	1 – 2.5 micron	8.5 – 8.7

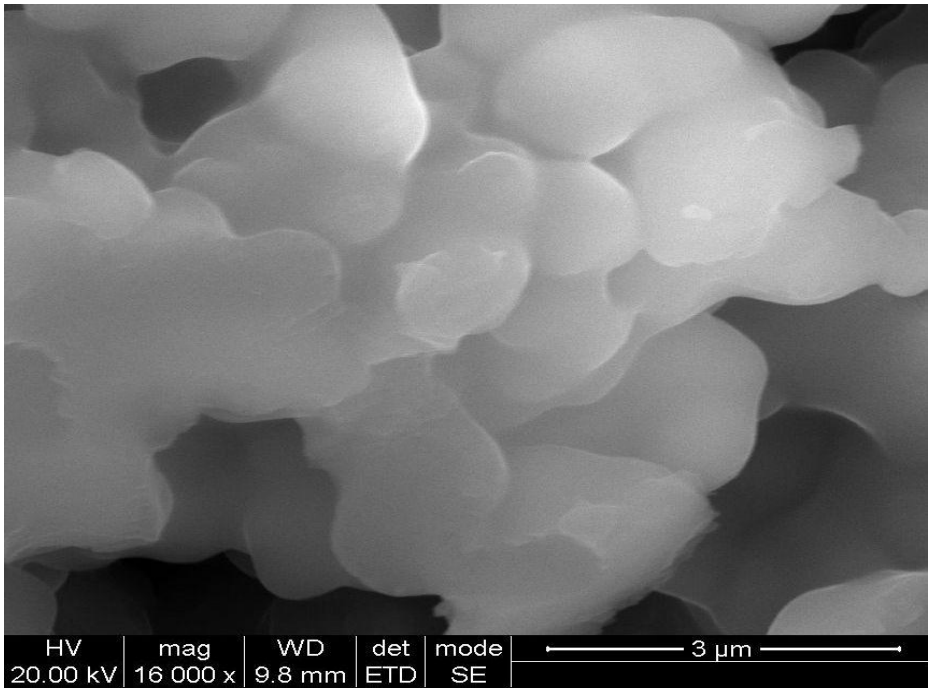
Preliminary Qualitative Phyto chemical tests procedure and interpretation of results

S.NO	PROCEDURE	INFERENCE
1.	**Calcium**	Presence of Calcium
2.	**Sulphate**	Absence of Sulphate
3.	**Chloride**	Absence of Chloride
4.	**Carbonate**	Presence of Carbonate
5.	**Starch**	Absence of Starch
6.	**Iron**	Presence of Iron
7.	**Phosphate**	Presence of Phosphate
8.	**Tannic acid**	Absence of Tannic acid
9.	**Aluminium**	Presence of Aluminium
10.	**Magnesium**	Presence of Magnesium
11.	**Ammonium**	Absence of Ammonium
12.	**Mercury**	Presence of Mercury
13.	**Alkaloids**	Absence of Alkaloids
14.	**Reducing Sugar**	Absence of Reducing sugar
15.	**Silicate**	Presence of Silicate
16.	**Copper**	Absence of Copper
17.	**Sodium**	Presence of Sodium
18.	**Lead**	Absence of Lead
19.	**Fluoride And Oxalate**	Absence of Fluoride and Oxalate
20.	**Unsaturated compounds**	Presence of unsaturated compunds

SOPHISTICATED ANALYTICAL INSTRUMENT FACILITY
IITM,CHENNAI-36
PERKIN ELMER OPTIMA 5300DV ICP-OES

SampleID	Analyte	Mean
DL=Below detection limit		
Sarva Noi Linga Chenduram		
	As193.696	BDL
	Al 308.215	BDL
	B 249.773	313.624 mg/L
	Ca 317.933	BDL
	Cd 226.502	BDL
	Cu 324.754	BDL
	Fe 238.204	BDL
	Hg253.652	4.251 mg/L
	K 766.491	BDL
	Mg 257.610	BDL
	Na 588.995	468.658 mg/L
	P 214.914	15.249 mg/L
	Pb 230.204	BDL
	S 181.975	89.657mg/L
	Si 251.611	8.775 mg/L

PARTICLE SIZE OF SARVA NOI LINGA CHENDURAM



Annexure III
Certificates

NATIONAL INSTITUTE OF SIDDHA
(An Autonomous Body under Department of AYUSH)
Ministry Of Health & Family Welfare, Government of India

Tambaram Sanatorium, Chennai - 600 047
Tel : 044-22411611 Fax : 044-22381314
E-mail : nischennaisiddha@yahoo.co.in
Website : www.nischennai.org

Name: DR. R. RADHA KRISHNAN. REG. NO 30101203
Title: PRE CLINICAL AND CLINICAL STUDY ON AZHAL KEEL VAYU AND THE DRUG OF CHOICE IS SARVANGI LINGA CHENDURAM (INTERNAL) . MAASHA THYLUM (EXTERNAL)
No. NIS/IEC/2011/3/03 - 24/12/2011

DECSION

Opinion of the Institutional Ethics Committee – Please Check one
✓ Approval _____ Modifications required prior to approval (Please specify one space below) _____ Disapproval Date of review: _____ K. Manickavasakam (Dr. K. MANICKAVASAKAM) Member Secretary Signed: _____ (Please print name) Dr.V.SUBRAMANIAN Chair person (Please delee as appropriate, Chairperson, Secretary)
Modifications needed Modification given to candidate
The research proponent is hereby informed that the Institutional Ethics Committee will require the following: 1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days 2. The progress report to be submitted to the IEC atleast annually 3. Upon completion of the study, a final study status report needs to submitted to the IEC

IAEC PROTOCOL NO :- 1048/ac/09/CPCSEA/403/201

20/12/2011

CERTIFICATE

This is certify that the project title. Preclinical and clinical Study on Azhl kelvayu (Osteoarthritis) and the Drug of choice of 'Sarva Roi Ling Chenduram'

has been approved by the IAEC.

Prof. Dr. K. Manickavasakam
Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Dare
Name of CPCSEA nominee:

Signature with date

K. Manickam

Chairman/Member Secretary of IAEC:

B. Jayachandran

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

The Tamil Nadu Dr. M.G.R. Medical University

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to ~~Mr~~/~~Ms~~/Dr.....R. RADHAKRISHNAN.....

for participating as a ~~Resource~~ ~~Person~~ / Delegate in the VII Workshop

on **"Research Methodology & Biostatistics"**

for AYUSH Post-Graduates & Researchers

organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University

from 6th Feb. 2012 to 10th Feb. 2012.

DR. MAYILVAHANAN NATARAJAN
M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. (Orth. Onco.) F.R.C.S. (Eng) D.Sc.
7th VICE CHANCELLOR

Dr. R. SRILAKSHMI, DCH, Ph.D.
REGISTRAR

Dr. N. KABILAN, M.D. (Siddha)
READER, DEPT. OF SIDDHA

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600 106
सिध्द केन्द्रीय अनुसंधान संस्थान, अरुम्बाक्कम, चेन्नई- 600106
Siddha Central Research Institute
Arignar Anna Govt. Hospital Campus, Arumbakkam, Chennai-600 106
(Central Council for Research in Siddha, Department of AYUSH,
Ministry of Health & Family Welfare, Govt. of India)
Phone: 044-2621 49 25,
Tele Fax: 044 26214809,
E.mail: crisiddha @ gmail.com
Web: www.crisiddha.tn.nic.in

06.02.2012

CERTIFICATE

Certified that the minerals submitted for identification by Dr.R.Radhakrishnan, II year Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 are identified as Lingam – Red sulphide of mercury, Venkaram – Borax and Indhuppu – Sodium chloride.

(R.Shakila)
Research Officer (Chemistry)

(K.Meenakshi Sundara Moorthy)
Asst. Director- In charge

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **Sarva Noi Linga Chenduram** (Internal) and **Maasha thylum(Ulunthu)** (External) for the management of **Azhal Keelvayu** (Osteoarthritis) taken up for Post Graduation Dissertation studies by **Dr.R.Radhakrishnan**, M.D.(S), II year Department of Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Organoleptic characters / Experience, Education & Training/ Morphology / Micromorphology / Microscopical/ Taxonomical methods.

Citrus limon (Linn.) Osb. (Rutaceae), Fruit
Sida cordifolia Linn. (Malvaceae), Root
Phaseolus mungo Linn. (Fabaceae), Seed
Ricinus communis Linn. (Euphorbiaceae), Root
Aconitum heterophyllum Wall.ex Royle (Ranunculaceae), Root
Alpinia galanga (Linn.) Willd. (Zingiberaceae), Rhizome
Tragia involucrata Linn. (Euphorbiaceae), Root
Asparagus racemosus Willd. (Liliaceae), Root

Certificate No: NIS/MB/39/2012

Date: 21-3-12

Authorized Signatory
Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA

SOPHISTICATED ANALYTICAL INSTRUMENT FACILITY
INDIAN INSTITUTE OF TECHNOLOGY, MADRAS
Chennai - 600 036. INDIA

CERTIFICATE

Certified that mineral drug **SARVA NOI LINGA CHENDURAM** formulated by **Dr.R.RADHA KRISHNAN** III Year M.D(S) Department of Maruthuvam, National Institute of Siddha , Tambaram Sanatorium was analysed (quantitative) by ICP-OES, HR-SEM and Physico chemical Analysis Methods at SAIF, IITM, Chennai-600 036, during October 2012.

Dr. R. MURUGESAN
Scientific Officer Gr.-I
Sophisticated Analytical Instrument Facility
Indian Institute of Technology, Madras
Chennai-600 036

Phone : 91-44-2257 4935 Fax : 91-44-2257 0545, 2257 0509
e-mail : saif@iitm.ac.in http://www.saif.iitm.ac.in

Annexure IV

Proforma

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASAR PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

PRE CLINICAL AND CLINICAL STUDY ON "AZHAL KEEL VAAYU " (OSTEO ARTHRITIS) AND THE DRUG OF CHOICE IS "SARVA NOI LINGA CHENDURAM" (INTERNAL) AND MAASHA THYLUM(EXTERNAL)

FORM I SCREENING & SELECTION PROFORMA

REG NO: 32101203 /2012-13

1. SI NO_____ 2 OP /IP NO:_____

3.NAME :_____ 4. AGE/SEX_____5.RELIGION : H / C / M / O

6.OCCUPATION / INCOME : _____

INCLUSION CRITERIA

- Age 30-60 yrs Yes/No
- Sex M/F
- Clinical symptoms of pain and swelling present in knee joints
  Crepitations,stiffness,restricted movements, minimal tenderness etc Yes/No
- Patient willing to under go lab and radiological investigations Yes/No
- Patient willingness for consent to include in the trial Yes/No

EXCLUSION CRITERIA

Rheumatoid arthritis	Y/N	Gouty arthritis	Y/N	Chickun gunya	Y/N
Tuberculosis of knee joints	Y/N	History of trauma	Y/N	Diabetes mellitus	Y/N
Hypertension	Y/N	Cardiac diseases	Y/N	Any other illness	Y/N

ADMITTED TO TRAIL : YES ☐ NO ☐ If Yes Serial NO: ☐

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
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DEPARTMENT OF MARUTHUVAM

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FORM l A - HISTORY PROFORMA ON ENROLLMENT

REG NO: 32101203/2012-13

1. Serial No :_____ 2. OP/IP No:_____

3. Name: _____ 4. Gender: Female/male

5. Age (years): _____DOB ☐☐ ☐☐ ☐☐☐☐
Date Month Year

6.Address:_____ _____
_____ _____

7.A.Occupation:---------- B. Nature of work----------

8. Educational Status: A) Illiterate ☐ B)Literate ☐ 9.Height: cms 10.Weight: kg

11. Complaints and Duration:

_____

_____

12. Habits of

A) Smoking	1. Yes; duration _____ years;	Number -	2.No
B) Alcoholism	1. Yes; duration _____ years;	Quantity-ml	2.No
C) Tobacco chewing	1. Yes; duration _____ years;	2.No	
D) Betel chewing	1. Yes; duration _____ years;	2.No	

13.Dietry style A.Pure vegetarian ☐ B.Non-vegetarian ☐ C. Mixed diet ☐

14.Treatment History:

Had the patient been treated before with allopathy drug? A)Yes ☐ B)No ☐

15. Menstrual Historty:

Date:

Station:

Signature of the investigator

Signature of the lecturer

Signature of HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
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FORM II CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS

1. S NO ---------- 2. OP/IP NO ---------- REG NO: 32101203/2012-13

3. NAME ---------- 4.GENDER M/F 5. DATE OF ASSESSMENT :----------

Initial (0^{th} day) ☐ 12^{th} day ☐ 24^{th} day ☐ 36^{th} day ☐ th day ☐

SIDDHA SYSTEM OF EXAMINATION

1. ENNVAGAI THERVU: [EIGHT-FOLD EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

Naadi	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day	Naadi	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Vali						Iyya vali					
Azhal						Vali Iyyam					
Iyyam						Azhal Iyyam					
Vali azhal						Iyya Azhal					
Azhal vali											

II. NAA:[TONGUE]

	0th Day	**12th Day**	**24th Day**	**36th Day**	**48th Day**
Colour	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal
Taste	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None
Coating	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

Fissure	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Saliva	Normal/ Increased/ Decreased	Normal/ Increased Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased
Dryness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Glossitis	Present/ Absent	Present /Absent	Present/ Absent	Present/ Absent	Present/ Absent
Baldness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

III.NIRAM: [COMPLEXION**]**

0^{th} Day	12th day	24^{th} Day	36^{th} Day	48^{nd} Day
Dark/ Yellowtinted/ Wheatish brown/ Pale	Dark/ Yellowtinted/ Wheatish brown/ Pale	Dark/ Yellowtinted/ Wheatish brown/ Pale	Dark/ Yellowtinted/ Wheatish brown/ Pale	Dark/ Yellowtinted/ Wheatish brown/ Pale

IV.MOZHI: [VOICE]

0^{th} Day	12th day	24^{th} Day	36^{th} Day	48^{nd} Day
Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Lowpitched

V.VIZHI: [EYES] (Lower palpabrel conjunctiva)

0^{th} Day	12th day	24^{th} Day	36^{th} Day	48^{nd} Day
Yellow Red / Pale/Normal	Yellow Red/ Pale/Normal	Yellow Red/ Pale/Normal	Yellow Red/ Pale/Normal	Yellow Red/ Pale/Normal

VI. MALAM; [BOWEL HABITS / STOOLS]

	0^{th} Day	12^{th} Day	24^{th} Day	36^{nd} Day	48^{th} day
Colour	Dark/ Yellow/ Pale/Others	Dark/ Yellow/ Pale/Others	Dark/ Yellow Pale/Others	Dark/ Yellow/ Pale/Others	Dark/ Yellow/ Pale/Others
Consistency	Solid/ Semisolid Watery	Solid/ Semisolid Watery	Solid/ Semisolid Watery	Solid/ Semisolid Watery	Solid/ Semisolid Watery
Stool bulk	Normal/ Reduced	Normal /Reduced	Normal/ Reduced	Normal/ Reduced	Normal/ Reduced
Constipation	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Diarrhoea	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

VII. URINE EXAMINATION:

NEER KURI	**0th Day**	**12th Day**	**24 th Day**	**36nd Day**	
Niram [Colour]	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear
Manam [Odour]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Nurai [Froth]	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased
Edai [Sp.gra]	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced
Enjal [Deposits]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Volume	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

NEIKURI	**0th day**	**12th day**	**24th day**	**36th day**	**48th day**
Serpentine fashion					
Annular/Ringed fashion					
Pearl beaded fashion					
Mixed fashion					
Other fashion					

VIII. SPARISAM: [PALPATORY PERCEPTION]

0th Day	12th Day	24th Day	36th Day	48nd Day
Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat

THEGI: [TYPE OF BODY CONSTITUTION]

Vatham predominant		Kabam predominant	
Pitham predominant		Thondha udal	

6.NILAM: [LAND WHERE PATIENT LIVED MOST]

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Palai ☐

(Hilly terrain) (Plains) (Coastal belt) (Aridregions) (Forestrange)

7.KAALAM

Kaarkalam	☐	Pinpanikalam	☐
Koothirkalam	☐	Ilavenil	☐
Munpanikalam	☐	Muthuvenil	☐

8. GUNAM

Sathuvam ☐ Rasatham ☐ Thamasam ☐

IMPORIGAL (SENSORY ORGANS)

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Mei (Skin)					
Vaai (Buccal Cavity)					
Kann (Eye)					
Mooku (Nose)					
Sevi(Ear)					

7. KANMENTHIRIYAM (MOTOR ORGANS)

Kanmenthiriyam	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Kai (upper limb)					
Kaal (lower limbs)					
Vaai (buccal cavity)					
Eruvai (excretory organs)					
Karuvai (reproductive organs)					

8. KOSANGAL(Sheath)

Kosangal	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Annamaya Kosam					
Pranamaya kosam					
Manomaya kosam					
Vignanamaya kosam					
Ananthamaya kosam					

12. MUKKUTRAM:[AFFECTION OF THREE HUMORS]
A)VATHAM:

Vatham	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Praanan					
Abaanan					
Samaanan					
Udhaanan					
Viyaanan					
Naagan					
Koorman					
Kirukaran					
Devathathan					
Dhananjeyan					

B) PITHAM:

Pitham	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Analapitham					
Prasakam					
Ranjakam					
Aalosakam					
Saathakam					

C) KABAM:

Kabam	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Avalambagam					
Kilethagam					
Pothagam					
Tharpagam					
Santhigam					

13. SEVEN DHATHUS: (7 SOMATIC COMPONENTS)

Udal thathukkal	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Saaram[Chyme]					
Senneer[Blood]					
Oon[Muscle]					
Kozhuppu[Fat]					
Enbu[Bones]					
Moolai [Bonemarrow]					
Sukkilam/Suronitham[Genital discharges]					

14. SYSTEMIC EXAMINATION:

Systemic examination	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Locomotor system					
Cardio Vascular System					
Respiratory system					
Gastro Intestinal system					
Central Nervous System					
Urogenital system					
Endocrine System					

15. GENERAL EXAMINATION:

General Examination:	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Height (cms)					
Weight (kg)					
BMI					
Temperature(°F)					
Pulse rate (pe rmin)					
Heart rate (per min)					
Respiratoryrate(permin)					
Blood pressure(mm/Hg)					
Pallor					
Jaundice					
Cyanosis					
Lymphadenopathy					
Pedal edema					
Clubbing					
Jugular venous pulsation					

16. CLINICAL SYMPTOMS

S.no	CLINICAL SYMPTOMS	0 th day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
1	Pain					
2	Swelling					
3	Early morning stiffness					
4	Restricted movements (Fully/Partial/No)					
5	Minimal tenderness					
6	Crepitations					

CLINICAL EXAMINARTION OF KNEE JOINT

I. INSPECTION

S.no	Inspection	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
1	Attitude:					
2	Shape					
3	Knee joint swelling					
4	Skin over the knee joints					
5	Muscle wasting					
6	Deformity Genu varum					

II. PALPATION

S.no	Palpations	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
1	Tenderness					
2	crepitation					
3	warmth					

MOVEMENTS

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
A.**PAIN** **Onset**: Sudden/Gradual					
B.Early morning Stiffnes (Present/absent)					
C.Nature of pain (Mild/ Moderate/ Severe)					
D.Aggravating factor- Movement (Yes/No)					
E.Relieving factor – Rest (Yes/No)					
F.Tenderness (Present/absent)					
G.Restriction: (Fully/Partial/No)					

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

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DEPARTMENT OF POTHUMARUTHUVAM

PRE CLINICAL AND CLINICAL STUDY ON "AZHAL KEEL VAAYU " (OSTEO ARTHRITIS) AND THE DRUG OF CHOICE IS "SARVA NOI LINGA CHENDURAM" (INTERNAL) AND MAASHA THYLUM(EXTERNAL)

FORM III

LABORATORY PARAMETERS-CHART

1. OP/IP No: _____ 2.S. No:_____ 3.Reg no: 32101203/2010-11

4. Name: _____5. Age/sex : _____

BLOOD INVESTIGATION		NORMAL VALUES	BEFORE TMT	AFTER TMT
HB(gms%)		M:13-18 W:11-16		
T.RBC(million cells /cu.mm)		M:4.5-6.5 W:3.5-5.5		
ESR (mm)	½ hr.	M:0-10 W:0-20		
	1 hr.			
T.WBC (cells /cu.mm)		4000-11000		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	20-35		
	Monocytes	2-10		
	Esonophils	1-6		
	Basophils	0-1		

Blood Investigation		Normal Values	Before TMT Date:	After TMT Date
Blood glucose (mg/dl)	Fasting	70-100		
	PP	80-140		
	Random	100-140		
Lipid profile (mg/dl)	Serum cholesterol	150-250		
	HDL	30-60		
	LDL	Upto 130		
	VLDL	40		
	TGL	Upto 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
LFT (mg/dl)	Total bilirubin	0.3-1		
	Direct bilirubin	0.1-0.3		
	Indirect bilirubin	0.2-0.8		
	Serum total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	Serum calcium	9-11		
	Serum phosphorous	2-5		
	SGOT (IU/L)	6-18		
	SGPT (IU/l)	3-26		
	Alkaline phosphatase mg/dl	3-12		

Specific investigation	Before TMT Date:	After TMT Date:
RA factor		
CRP		

URINE INVESTIGATION	Before TMT(with Date)	After TMT (With Date)
Albumin		
Fasting sugar		
PP sugar		
Random Sugar		
Deposits		
Bile salts		
Bile pigments		
NEIKURI		
MOTION TEST		
Ova		
Cyst		
Occult blood		

X ray changes

	Before TMT (with Date)	After TMT (With Date)
X ray of affected knee joints		

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

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FORM IV-E

WITHDRAWAL FORM

S. NO:_____ OPD/ IPD NO:_____ REG NO: 32101203/2012-13

NAME:_____ AGE/SEX :_____

DATE OF TRIAL COMMENCEMENT:_____

DATE OF WITHDRAWAL FROM THE TRIAL:_____

REASONS FOR WITHDRAWAL:

- Long absence at reporting Yes / No
- Irregular treatment: Yes / No
- Shift of locality Yes / No
- Increase in severity of symptoms Yes / No
- Development of severe adverse drug reactions Yes / No

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

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FORM IV –A (DRUG COMPLIANCE FORM)

S. NO:_____ OPD/ IPD NO:_____ REG NO: 32101203/2012-13

NAME:_____ AGE/SEX :_____

Name of the drug : Sarva noi linga chenduram (internal)

Maasha thylum (external)

Drugs issued: (Nos) Drugs issued: (Nos)

Drugs returned:(Nos) Drugs returned: (Nos)

S.NO	DATE	DRUG TAKEN TIME			
		MORNING/TIME		EVENING/TIME	
Day 1					
Day 2					
Day 3					
Day 4					
Day 5					
Day 6					
Day 7					
Day 8					
Day 9					
Day 10					
Day 11					
Day 12					

Date :
Station:
Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

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FORM IV –A (DRUG COMPLIANCE FORM)

S. NO:_____ OPD/ IPD NO:_____ REG NO: 32101203/2012-13

NAME:_____ AGE/SEX :_____

Name of the drug : Sarvo noi linga chenduram (internal)

Maasha thylum (external)

Drugs issued: (Nos) Drugs issued: (Nos)

Drugs returned:(Nos) Drugs returned: (Nos)

DAYS	DATE	DRUG TAKEN TIME			
		MORNING/TIME		EVENING/TIME	
Day 13					
Day 14					
Day 15					
Day 16					
Day 17					
Day 18					
Day 19					
Day 20					
Day 21					
Day 22					
Day 23					
Day 24					

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

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FORM IV –A (DRUG COMPLIANCE FORM)

S. NO:_____ OPD/ IPD NO:_____ REG NO: 32101203/2012-13

NAME:_____ AGE/SEX :_____

Name of the drug : Sarva noi linga chenduram (internal)

Maasha thylum (external)

Drugs issued: (Nos) Drugs issued: (Nos)

Drugs returned: (Nos) Drugs returned: (Nos)

S.NO	DATE	DRUG TAKEN TIME			
		MORNING/TIME		EVENING/TIME	
Day 25					
Day 26					
Day 27					
Day 28					
Day 29					
Day 30					
Day 31					
Day 32					
Day 33					
Day 34					
Day 35					
Day 36					

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

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PRE CLINICAL AND CLINICAL STUDY ON "AZHAL KEEL VAAYU " (OSTEO ARTHRITIS) AND THE DRUG OF CHOICE IS "SARVA 6NOI LINGA CHENDURAM" (INTERNAL) AND MAASHA THYLUM(EXTERNAL)

FORM IV –A (DRUG COMPLIANCE FORM)

S. NO:_____ OPD/ IPD NO:_____ REG NO: 32101203/2012-13

NAME:_____ AGE/SEX :_____

Name of the drug: Sarva noi linga chenduram (internal)

Maasha thylum (external)

Drugs issued: (Nos) Drugs issued: (Nos)

Drugs returned: (Nos) Drugs returned: (Nos)

DAYS	DATE	DRUG TAKEN TIME			
		MORNING/TIME		EVENING/TIME	
Day 37					
Day 38					
Day 39					
Day 40					
Day 41					
Day 42					
Day 43					
Day 44					
Day 45					
Day 46					
Day 47					
Day 48					

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

தேசிய சித்த மருத்துவ நிறுவனம், சென்னை 47
அயோத்திதாசர் பண்டிதர் மருத்துவமனை

அழல் கீல்வாயு நோய்க்கான சித்த மருந்தின் (சர்வ நோய் இலிங்க செந்தூரம் மற்றும் மாஷ தைலம் - உளுந்து தைலம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

FORM IV B தகவல் படிவம்

முதன்மை ஆராய்ச்சியாளர் பெயர் : Dr.R. ராதாகிருஷ்ணன்
நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானடோரியம்
சென்னை- 47

Dr.ராதாகிருஷ்ணன் ஆகிய நான் தேசிய சித்த மருத்துவமனையில் பட்ட மேற்படிப்பு பயின்று வருகிறேன். அழல் கீல்வாயு என்னும் நோயானது பெருமூட்டுகளை பாதிக்கும் நோயாகும். இந்நோயானது மூட்டுகள் திமிர்ந்து காணும், மூட்டுகளில் வீக்கம்,வலி நடக்க முடியாமை, நடக்கும் போது நட்டையுடைதல் போன்ற ஒலி, சில நேரங்களில் சுரம் காணுதல், ஆகிய குறிகுணங்கள் காணும். இந்நோய்க்கு தேசிய சித்த மருத்துவமனையில் பல சித்த மருந்துகள் பயன்படுத்தப்பட்டு வருகின்றது. சித்த மருத்துவ பட்ட மேற்படிப்பில், ஆய்வின் ஒரு பகுதியாக புதிய மருந்துகளை பயன்படுத்தும் நோக்கில் சர்வ நோய் இலிங்க செந்தூரம் இந்நோய்க்கு வழங்க பரிந்துரை செய்கிறோம். இந்த மருந்தின் செய்முறை, அளவு, அனுபானம் மற்றும் மருத்துவ பயன்கள் அனைத்தும் அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. எந்தவித கட்டணமுமின்றி தாங்கள் இந்த மருந்தினை பெற்றுக்கொள்ளலாம். இந்த ஆய்வில் மருந்து உட்கொள்ளும் காலம் 48நாட்கள் ஆகும். 7 நாட்களுக்கு தொடர்ந்து மருந்து உண்டு பின் 5 நாட்களுக்கு மருந்து உண்ணாமல் பத்தியம் காக்க வேண்டும், இம்முறைப்படி (7+5) என இன்னும் 36 நாட்களுக்கு தொடர வேண்டும், வெளி மருந்தாக மாஷ தைலம்(உளுந்து தைலம்) 50 மிலி 48 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவ வேண்டும். வெளி நோயாளர்கள் 12 நாட்களுக்கு ஒரு முறை மருத்துவமனைக்கு வரவேண்டும். 48நாட்கள் மருந்து உட்கொள்ளும் காலம் முடிந்த பிறகு நோய்க்கான குறிகுணங்கள் மற்றும் ஆய்வக பரிசோதனைகள் இவற்றின் முடிவுகளின் அடிப்படையில் மருந்தின் பரிகரிப்புத்திறன் கண்டறியப்படும்.

இந்த ஆய்வு சம்பந்தமாக சில கேள்விகளை தங்களிடம் கேட்க இருக்கிறேன். தங்களிடமிருந்து பெறப்படும் கருத்துக்கள் மற்றும் குறிப்புகள் அனைத்தும் நம்பிக்கையாக பதிவு செய்யப்படும்.இந்த ஆய்வில் தங்களை உட்படுத்திக்கொள்வதின் மூலம் எந்த வகையிலும் பாதிப்புக்குள்ளாக மாட்டீர்கள் என உறுதி அளிக்கிறேன்.
எந்தவித வற்புறுத்தலுமின்றி, இந்த ஆய்வில் பங்கேற்கவும், இந்த ஆய்வு சம்பந்தமாக கேட்கப்படும் கேள்விகளுக்கு பதில் கூறவும் தங்களுக்கு முழு சுதந்திரம் அளிக்கப்படுகிறது. இந்த ஆய்வில் பங்கேற்பதற்கு எந்த சன்மானமும் வழங்கப்படமாட்டாது. ஆனால், ஆய்வு முழுவதும் எனது மேற்பார்வையிலும், தங்கள் உடல்நலன் குறித்த தனி கவனத்திலும் ஆய்வு மேற்கொள்ளப்படும். அழல் கீல்வாயு நோய்க்கான புதிய மருந்தின் பரிகரிப்புத்திறனை சமூகத்திற்கு உணர்த்தும் வகையில் இந்த ஆய்வு மேற்கொள்ளப்படுகிறது, இந்த ஆய்வில், மருந்து உட்கொள்ளும் காலத்தில் வாய் நாற்றம், உணவு உண்ண முடியாமை, உமிழ் நீர் வடிதல், வாய், தொண்டை, மற்றும் வயிற்றில் எரிச்சல் போன்ற மாறுபட்ட குறிகுணங்கள் தொடர்ந்து இருக்கும் பட்சத்தில், முதன்மை ஆராய்ச்சியாளரான என்னிடம் தெரிவிக்கப்பட்டு, தேசிய சித்த மருத்துவமனையில் அதற்க்கான தீர்வு வழங்கப்படும். இந்த ஆய்வினைத் தொடர தங்களுக்கு விருப்பம் இல்லையெனில், எப்பொழுது வேண்டுமானலும் ஆய்வின் இடையில் விலகிக்கொள்ளவும், மருத்துவமனையில் வழங்கப்படும் இந்நோய்க்கான வழக்கமான மருந்துகளை பெற்றுக்கொள்ளவும் அறிவுறுத்தப்படுகிறீர்கள்.

இந்த ஆய்வில் சேகரிக்கப்படும் விபரங்கள் அனைத்தும் தங்களுக்கும் முதன்மை ஆராய்ச்சியாளரான எனக்கும் இடையில் இரகசியமாக வைக்கப்படும். கேள்வி பதில் வடிவத்தில் தங்களிடம் கேள்விகள் கேட்கப்படும். அனைத்துப் படிவங்களிலும் தங்களின் பெயர் தவிர்க்கப்பட்டு ஆய்வாளரால் தங்களுக்கென தனிக் குறியீடு வழங்கப்படும். அந்தக் குறியீடு ஆய்வாளருக்கு மட்டுமே தெரிந்ததாக இருக்கும். நீங்கள் இந்த ஆய்வில் பங்கேற்க விருப்பப்பட்டால், திட்ட வரைவு தகவல் படி தேர்வு செய்யப்படுவீர்கள்.

நீங்கள் இந்த ஆய்வில் பங்கேற்கும் முன், இந்த ஆய்வினைப் பற்றிய மேலும் விபரங்கள் பெற வேண்டுமென விருப்பப்பட்டால், இந்த ஆய்வின் முதன்மை ஆராய்ச்சியாளர் மற்றும் தேசிய சித்த மருத்துவமனை, பட்ட மேற்படிப்புத்துறை மாணவர் Dr.R. ராதாகிருஷ்ணன் ஆகிய என்னை 9884400971 என்ற எண்ணில் தொடர்பு கொள்ளலாம். மேலும், நீங்கள் இந்த ஆய்வில், உங்களது பங்கேற்பு மற்றும் உரிமை பற்றி தெரிந்து கொள்ள தேசிய சித்த மருத்துவமனை, தலைவர்/செயற்க்குழு உறுப்பினர் அவர்களையும் 91-44-22411611 என்ற எண்ணில் தொடர்பு கொள்ளலாம்.

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM
PRE CLINICAL AND CLINICAL STUDY ON "AZHAL KEEL VAAYU " (OSTEO ARTHRITIS) AND THE DRUG OF CHOICE IS "SARVA NOI LINGA CHENDURAM" (INTERNAL) AND MAASHA THYLUM(EXTERNAL)

FORM IV B – INFORMATION SHEET

Name of the Principal Investigator: Dr.R.Radha krishnan
Name of the Institution : National Institute of Siddha, Tambaram Sanatorium Chennai-47.

- I, Dr.R.Radhakrishnan Studying M.D(S) in National Institute of Siddha, Chennai. The disease called azhal keel vayu(osteo arthritis) Osteo arthritis (OA) is a most common persistent degenarative arthritis, occurring throughout the world and in all ethnic groups It includes the symptoms like, pain in the knee joint, swelling, restricted movements, crepitation.This condition is being treated is NIS with many siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicine, we propose to study the Sarva noi linga chenduram and maasha thylum[ulunthu thylum) formulation for treating the condition. This formulation has been mentioned in siddha literature and empirical evidence with contemporary tools is required for documentation. You can receive medicines free of cost. sarva noi linga chenduram(Internal medicine-130mgs BD with Honey for 28 days in a duration of 48 days) and Maasha Thylum (External medicine). The diagnosis tests will be carried out free of cost. We will assess the effect of treatment after completion of 48 days of treatment using clinical and lab parameters.

- In this regard, we need to ask you few questions. We will maintain confidentiality of your comments and data obtained from you. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

- Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. You can choose not to answer any specific question. There is no specific benefit for you if you take part in the study, but you will be under our clinical monitoring and specific attention will be given for your health. Taking part in the study may be of benefit to the community, as it may help us to develop medicine for azhal keel vayu. In case of any adverse symptoms during the treatment viz, apthous ulcers, difficulty to take food and water sometimes to speak, bad breath, thickened salivary secretion and burning sensation if felt in mouth, throat and stomach which is expected for few .patients during the treatment, shall be reported to PIs and care will be taken in NIS for relief. You can withdraw from the study at the midst of treatment period, if you are not interested to continue and you will receive our usual treatment without condition.

- The information we will collect in this study, will remain between you and the principal investigator. We will ask you a few questions through questionnaire. We will not write your name on different forms which sent to different investigating/analysis sections and we will use a code instead given by the principal investigator. Only the principal investigator will know the key to this code which will be kept in safe custody. If you agree to be a participant in this study, you will be screened as per the study protocol.

- If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.R.Radhakrishnan Studying M.D(S) scholar cum principal investigator of this study, attached to the National Institute of Siddha, Chennai (Mobile phone no:9444182233). You can also contact the Chairman/Member-secretary of Ethics committee, National Institute of Siddha, Chennai – 600047, Tel no: 91-44-22411611, for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம், சென்னை- 47

அயோத்திதாசர் பண்டிதர் மருத்துவமனை

அழல்கீல் வாயு நோய்க்கான சித்த மருந்துகளின் (சர்வ நோய் இலிங்க செந்தூரம் மற்றும் மாஷ தைலம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான ஒப்புதல் படிவம்

ஒப்புதல் படிவம்

நான் மேற்கூறிய தகவல் படிவத்தை படித்து அல்லது படிக்க கேட்டுக் கொண்டேன். இது தொடர்பான விளக்கங்களையும் கேட்டு தெரிந்துகொண்டேன்.எந்த வித வற்புறுத்தலின்றி என் சொந்த விருப்பத்தின் பேரில் என்னை இந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கின்றேன். எனக்கு விருப்பம் இல்லாத பட்சத்தில் இந்த ஆராய்ச்சியில் இருந்து என்னை எப்போது வேண்டுமானாலும் விடுவித்து கொள்ளும் உரிமையை பெற்றுள்ளேன் என்பதையும் அறிவேன்

தேதி :

இடம் :

கையொப்பம்

பெயர்

சாட்சிக்காரர் கையொப்பம்

பெயர்

உறவுமுறை:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASAR PANDITHAR HOSPITAL
DEPARTMENT OF POTHUMARUTHUVAM

FORM IV C CERTIFICATE OF CONSENT

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".
Date:

Signature of the participant

In case of illiterate participant,

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness

Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

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FORM IV D DIETARY ADVICE FORM

✓ **சேர்க்க வேண்டிய உணவுகள்**

* **காய்கள்** : கத்திரி பிஞ்சு, முருங்கை பிஞ்சு, அவரை பிஞ்சு, ஆகியவை சேர்க்க வேண்டும்.
* **கீரைகள்** : பொன்னாங்கண்ணி, மணத்தக்காளி, மூக்கிரட்டை, தூதுவளை, வேளை கீரை, கறிவேப்பிலை, ஆகியவை சேர்க்க வேண்டும்,
* **பழங்கள்** : மாதுளை, ஆப்பிள், பேரீச்சை, அத்தி, நாவல், ஆகியவை சேர்க்க வேண்டும்.
* **அசைவம்** : வெள்ளாட்டுக்கறி, சிறு இறால் மீன் ஆகியவை சேர்க்க வேண்டும்,
* பால் சேர்க்க வேண்டும்.

✓ **சேர்க்க கூடாதவைகள்**

* உப்பு	பீர்க்கு
* பூசணி	புடலை
* மொச்சை	கொள்ளு
* காராமணி	கடுகு
* மந்தப் பொருள்	எண்ணெய்
* அதிக கைப்பு	அதிக கார்ப்பு
* புளிப்பு	பெண்போகம்
* வெற்றிலை,பாக்கு	புகையிலை

* மது அருந்துதல்
* ஈரமில்லா தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும்
* குளிர் காற்று படும்படியான இடத்தில் இருப்பதை தவிர்க்கவும்
* சுரம் உள்ள போது நீர்வடிவான கஞ்சி வகைகள் உண்ணவும்

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

DEPARTMENT OF POTHUMARUTHUVAM

PRE CLINICAL AND CLINICAL STUDY ON "AZHAL KEEL VAAYU " (OSTEO ARTHRITIS) AND THE DRUG OF CHOICE IS "SARVA NOI LINGA CHENDURAM" (INTERNAL) AND MAASHA THYLUM(EXTERNAL)

FORM –IV-F

ADVERSE DRUG REACTION FORM

Reg No:32101203/2012-13

Serial No: OP/IP No:

Name: Age: Gender: M/F

Date of trial commencement:

Date of the adverse reaction occur;

Description of Adverse reaction:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

ASSESSMENT FORM

FORM I	SCREENING AND SELECTION PROFORMA
FORM I	A HISTORY PROFORMA ON ENROLLMENT
FORM ll	CLINICAL ASSESSMENT ON ENROLLMENT
FORM ll A	CLINICAL ASSESSMENT DURING AND AFTER TRIAL
FORM lll	LABORATORY INVESTIGATION ON ENROLLMENT AND CONCLUSION OF TRIAL
FORM IV	ADRUG COMPLIANCE FORM
FORM IV B	INFORMATION SHEET
FORM IV C	CONSENT FORM
FORM IV D	DIETARY ADVICE FORM
FORM IV E	WITHDRAWAL FORM
FORM IV F	ADVERSE REACTION FORM

Bibliography

BIBLIOGRAPHY

1.Yoogi vaithiya chinthamani – Yoogi munivar

2.Noi nadal Noi muthal naadal thirattu part 1& 2- Dr.Ma.shanmugavelu

3.Anupoga vaithiya Navaneetham, part IV- Hackim Pa.Mu. Abdullah saibu

4.Viathiya sinthamni sigicha rathina deepam - pg no 202

5.C.kannusamipillai edition 2007sigicha ratna deepam, pg no 320

6.Sarakku suthi seimuraigal –Thiru. Anaivari Anandan

7.Gunapadam Mooligai vaguppu –ka.sa. Murugesa muthaliyar

8.Gunapadam thathu jeeva vaguppu -Dr.R.Thiyagarajan

9.Siddha maruthuvam pothu – Dr.Ka.Na Kuppusamy muthaliyar

10.Noi lla neri (siddha hygiene and preventive medicine)- Dr. Ko. Durairasan.

11.Siddha maruthuvanga surukkam – K.S. Uthamarayan

12.History of siddha medicine- N. Kandasamy pillai

13.T.V sambasivam pillai – Tamil - English dictionary Vol I

14.Udal thathuvam – Dr.Pu.Mu. Venugopal

15.Pathartha Guna vilakkam – C.Kannusamipillai

16.Dr.K.M. Natkaranis Indian Material Medica Vol I

17.Indian medicinal plants volume III

18.Indian material medica volume I

19.Wealth of india

20.Compendium of Indian medicinal plants, vol II- B.N mehrotra,Ram.P rastogi
Siddha materia medica (Mineral and vegetable kingdom)- Dr.Anaivari Anandan & Dr.M.s thulasimani

21.Davidson's principles and practice of medicine, 19 th edition -Christoper haslett, Edwin R.Chilver, Nicholas A.Boon, Nicki R.colledge

22.Clinical orthopaedic examination, V Edition- Ronlad MC. Race

23.B.D chaurasia Human Anatomy, 4 th edition ,Vol II

24.Manual of Practical medicine, II edition- R. Alagappan,

25.Text book of orthopaedics- John Ebnezar, III editon

26.www.freewebs.com/siddha papres / origina

27.www.healthpages. Org.

28.www.acsolutions.com/anatomy.php

29.www.jointhealing.com/pages/knee/knee

30.National institute of health, pain- clinical manual for nursing Practise pg no(1), mc caffery,m& beebe,a(1993)

http://www.southwestspineandpain.com/how-accurate-is-the-1-to-10-pain-scale/